Supreme Court, U.S.
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No.

IN THE

Supreme Court of the United States

MEDTRONIC VASCULAR, INC.,
Petitioner,

v.

CORDIS CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

A patentee who narrows the scope of a patent claim — either by amending its terms or by convincing the Patent and Trademark Office (PTO) that the existing terms are narrow enough to avoid prior art — should not be permitted to regain what it relinquished in the patent prosecution process. In *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), this Court held that, subject to limited exceptions, a narrowing amendment presumptively bars any application of the doctrine of equivalents, which otherwise would permit infringement by a device that is not literally within the terms of the patent claim but that differs from it only insubstantially. By contrast with this Court's analysis in *Festo*, however, the Federal Circuit has held that narrowing arguments presumptively have no effect on either literal infringement or infringement by equivalents.

The question presented is whether a patent claim allowed only after narrowing arguments were made to the PTO to distinguish prior art should be construed strictly in light of those arguments to limit claim scope both literally and by equivalents.

PARTIES TO THE PROCEEDING

The parties to the proceeding in the court of appeals included Medtronic AVE, Inc., Arterial Vascular Engineering, Inc., and Cordis Corporation. Boston Scientific Corporation, Scimed Life Systems, Inc., Johnson & Johnson, and Expandable Grafts Partnership were parties to the proceeding in the district court whose interests might be affected by the resolution of this case.

RULE 29.6 STATEMENT

Petitioner, Medtronic Vascular, Inc. (formerly known as Medtronic AVE, Inc.) is a wholly owned subsidiary of Medtronic, Inc. Medtronic Vascular, Inc. has no subsidiaries or affiliates that have issued shares to the public.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Medtronic Vascular, Inc. ("Medtronic") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-25a) is reported at 339 F.3d 1352. The opinion of the district court on post-trial motions (App., *infra*, 26a-116a) is reported at 194 F. Supp. 2d 323; the opinion of that court granting reconsideration in part (App., *infra*, 147a-155a) is unreported, but is available at 2002 U.S. Dist. LEXIS 9083. The opinion of the district court granting summary judgment of no literal infringement (App., *infra*, 120a-142a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on August 12, 2003. App., *infra*, 25.1a-25.2a. A timely petition for rehearing was denied on October 3, 2003. *Id.* at 145a-146a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

35 U.S.C. § 271(a) provides:

> Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.

STATEMENT OF THE CASE

This Court long has interpreted "the claims of a patent * * * in light of the proceedings in the PTO during the application process." *Festo Corp. v. Shoketsu Kinzoku Kogyo Ka-*

bushiki Co., 535 U.S. 722, 733 (2002); *see, e.g.*, *Sargent v Hall Safe & Lock Co.*, 114 U.S. 63, 73 (1885) (referring to the "history of the application for the patent as it passed through the patent-office" in determining the "proper construction of the claims allowed"). The public record of the give-and-take during patent prosecution provides a notice function to the public nearly equal to that of the patent claims themselves.

The Court likewise has insisted that any subject matter yielded during patent prosecution cannot be reclaimed in later infringement litigation. In *Festo*, the Court imposed a presumption that any narrowing amendment made to a patent claim, whether or not responding to a patent examiner's rejection, was necessary to convince the patent examiner to issue the patent. Unless the patentee can rebut that presumption, the scope of the amended claim limitation will be confined to its literal terms, so that even an insubstantial variation on that limitation will avoid infringement.

This case addresses the effect on claim scope of arguments made explicitly to quell the patent examiner's doubts by presenting a narrower view of claim terms *without* amending them. The Federal Circuit has made arguments of that kind virtually risk-free. Under the decision below, a patentee is constrained by narrowing arguments only if they clearly and unmistakably surrender specific subject matter. As the Federal Circuit sees it, the presumptions weigh *against* the surrender of subject matter despite the patentee's demonstrated need to narrow the meaning of its claims to distinguish them from the prior art. The Federal Circuit applies that presumption even where there is no question that a surrender has occurred, and the only issue is the scope of the surrender.

This Court should make clear that the presumption of surrender confirmed in *Festo*, and the Court's broader rule of strict claim construction in light of narrowing that occurs

during prosecution, apply to *arguments* as well as *amendments*. A narrowing *argument* offered to avoid a rejection of a patent claim should have the same effect as an *amendment* to a claim — presumptive exclusion from the claim's literal scope of the subject matter discussed and distinguished, and presumptive preclusion of the doctrine of equivalents.

A. The Legal Setting: The Doctrine of Equivalents, Amendment-Based Estoppel, Argument-Based Estoppel, and Prosecution Disclaimer

This case addresses the intersection of several important principles of patent law. Foremost among these is the principle that patent claims must be interpreted in light of the prosecution history of the patent. *Festo*, 535 U.S. at 733. What a patentee says and does in the PTO to obtain the patent may determine the practical scope of the patent claims ultimately allowed, affecting both the interpretation of the literal claims and the availability of the doctrine of equivalents to extend the protective scope of those claims.

The doctrine of equivalents prevents a patent from losing all force simply because a rival device insubstantially modifies one claim element so as to fall outside the literal terms of the patent claim.[1] The doctrine permits a finding of infringement even if the accused device does not literally satisfy every element of a patent claim, so long as the device meets every element *either* literally *or* by a feature that differs only insubstantially from the element's literal terms. *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997).

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[1] For brevity, we refer only to patentable "devices" or "products," although the same analysis applies to patentable methods and processes.

A patentee's statements and actions while prosecuting the patent may preclude application of the doctrine of equivalents. This "prosecution history estoppel" may arise either from a narrowing *amendment* made to a claim element or from an *argument* made to persuade the patent examiner that the claimed invention embodied a patentable advance over the prior art. *E.g.*, *Festo*, 535 U.S. at 734; *Allen Eng'g Corp.* v. *Bartell Indus., Inc.*, 299 F.3d 1336, 1350 (Fed. Cir. 2002). *Festo* addressed prosecution history estoppel arising from the amendment of the patent claim. Amendment-based estoppel presumptively arises from *any* narrowing claim amendment, and presumptively bars *all* application of the doctrine of equivalents unless the patentee can show that the amendment falls within one of three narrow exceptions to the rule. *Festo*, 535 U.S. at 740-41. Similarly, argument-based estoppel arises from narrowing arguments made to the examiner to avoid having to amend a claim, and precludes infringement by the equivalents disclaimed in the prosecution argument at issue.

Those same arguments may also limit the literal scope of the claims under the related doctrine of prosecution disclaimer. Under this doctrine, a patentee who distinguishes subject matter from the claimed invention cannot recapture that subject matter by construing the claims more broadly during an infringement action. *See generally Storage Tech. Corp.* v. *Cisco Sys., Inc.*, 329 F.3d 823, 836 (Fed. Cir. 2003).

B. Factual Background: The Prosecution History of Cordis' Patents

This case arises from respondent Cordis Corporation's allegation that petitioner Medtronic infringed two patents that claim coronary stents for treatment of coronary artery disease: U.S. Patent Nos. 4,739,762 (the '762 patent), and 5,195,984 (the '984 patent). A stent is an expandable device that, when inserted into a blocked artery, props the artery open to allow blood flow. App., *infra*, 29a. The '762 patent

claims a slotted tube stent. The '984 patent is an improvement patent that claims a plurality of slotted tube stents of the type disclosed in the '762 patent, each pair connected with a single member parallel to the slots. *Id.* at 4a.

The specifications and claims of the two patents describe the stents themselves in virtually identical terms. Two claim limitations are at issue here. One limits the claim to stents with a "wall surface having * * * a plurality of slots formed therein" (the "slots formed therein" limitation). App., *infra*, 5a. The other limitation requires a "wall surface having substantially uniform thickness" (the "substantially uniform thickness" limitation). *Id.* at 6a.

1. The '762 Patent

The '762 patent issued in 1988 as a continuation-in-part of an application that resulted in an earlier stent patent, No. 4,733,665 (the '665 patent). The '665 patent had claimed a "plurality of intersecting elongate members," and disclosed as one of two preferred embodiments a "tubular shaped member" made of "stainless steel wire woven" into a "wire mesh tube." *Id.* at 8a-10a; *see id.* at 8a (Fig. 1A).

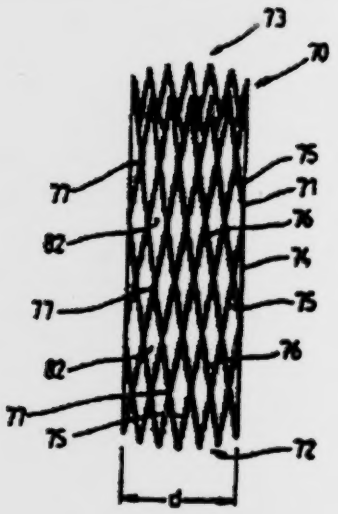

Fig. 1A of the '665 Patent

The continuation-in-part that resulted in the '762 patent carried over the other preferred embodiment, which showed a flat, continuous tubular wall with rectangular slot-like openings. The allowed claim reflected a corresponding change; it no longer described "intersecting elongate members," but rather claimed a "wall surface having * * * a plurality of slots formed therein." *Id.* at 57a-58a; *see also id.* at 30a (Fig. 1A).

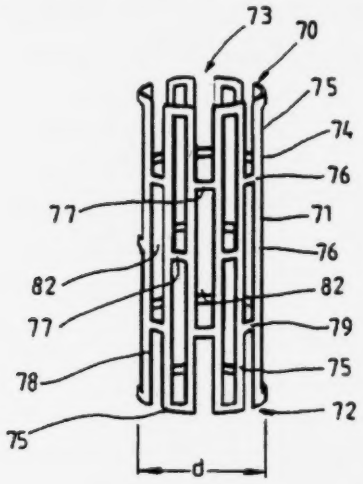

Fig. 1A of the '762 Patent

In 1997, Cordis asked the Patent and Trademark Office (PTO) to reexamine the '762 patent in light of several patents that had not been identified during the original prosecution, including the "Ersek" patent (No. 3,657,744).[2] In response to a rejection, based upon Ersek, of all of the '762 patent claims (C.A. App. A31391-31411), Cordis amended certain claims to add the "substantially uniform thickness" limitation that was already present in Claim 23 of the '762 patent (one of the claims asserted here). *See* C.A. App. A31421-22.

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[2] For brevity, we denote as "Cordis" both Cordis and the patentees who assigned the '762 and '984 patents to it.

The patentee used that amendment to distinguish Ersek on several grounds, pointing out several reasons why Ersek failed to disclose a substantially uniform wall thickness. Although some arguments highlighted the thickening at the junctions of the struts in Ersek, Cordis specifically argued to the PTO that the wall thickness of Ersek "varies throughout." App., *infra*, 17a; *see id.* at 15a ("varied at different points"). Cordis went so far as to quantify this pervasive variation, pointing out that, even apart from the wire junctions, the wall thickness of the Ersek device varied by 0.001 inch, ranging from a "minimum thickness of .0035 inches to a maximum thickness of .0045 inches." *Id.* at 15a; C.A. App. A31431-32.

2. The '984 Patent

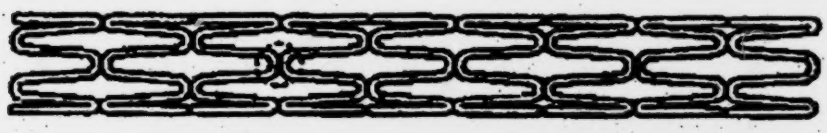
As noted above, the '984 patent claims a plurality of the stents claimed in the '762 patent linked by a single connector. While prosecuting the '984 patent, Cordis overcame two rejections over prior art bent-wire stents by relying on the "slots" and "substantially uniform thickness" limitations — limitations that are common to the '762 and the '984 patents. The examiner rejected several '984 claims as "clearly anticipated by Wiktor," *i.e.*, U.S. Patent No. 4,969,458. C.A. App. A32234; *see* App., *infra*, 4a. In response, Cordis argued that the Wiktor patent did not anticipate the '984 patent because:

> Wiktor discloses a single stent, or graft made up of coiled wire. *There is no wall surface having a plurality of slots*, nor slots disposed parallel to the longitudinal axis of each tubular member. *Applicant's claimed invention is not "coiled wire* wound in a special manner comprised of a number of groups or turns" as illustrated by Wiktor.

C.A. App. A32243 (emphasis added); *see* App., *infra,* 11a (emphasis added).

3. Medtronic's Stents

Three Medtronic products are relevant here. The MicroStent II, GFX and GFX2 are bent-wire stents that "consist of multiple sinusoidal segments fused together" so that each peak of one sinusoidal ring meets a valley of the next. App., *infra*, 48a; *id.* at 48a (diagram).



The stents vary in overall length and in number of peaks and valleys per ring. *Ibid.*

C. Proceedings Below

Cordis brought several actions for patent infringement against Medtronic and Boston Scientific Corporation ("BSC"), among others. As relevant here, Cordis alleged that Medtronic's manufacture and sale of its MicroStent II, GFX and GFX2 products (collectively, the "accused stents") infringed the '762 and '984 patents. The jurisdiction of the district court was invoked under 28 U.S.C. § 1338. The Medtronic and BSC actions were consolidated for some purposes but were tried separately.

Before trial, the district court construed the "slots formed therein" limitation as "limited to devices manufactured by removing material from a preexisting tube to form slots." *See* C.A. App. A239. The court later explained that "slots must be formed in the wall surface of the tubular member, as by removal of material." App., *infra,* 36a. The court defined "substantially uniform thickness" to mean "[t]he thickness at all points along the wall surface of the tubular member, both at its first and second diameters." *Id.* at 35a. Based on Cordis' representations to the PTO to distinguish the Ersek patent, the district court further found that "variances as little as .001 inch fall outside the scope of 'substantially uniform.'" *Ibid.*

The district court granted partial summary judgment to Medtronic, holding that, because the accused stents lack a preexisting wall, they do not satisfy the slots limitation and thus do not literally infringe any of the asserted claims of the '762 and '984 patents. App., *infra*, 138a. The court deferred until after trial the question whether Cordis was barred from asserting the doctrine of equivalents as to either the "slots formed therein" or "substantially uniform thickness" limitations.

A jury found all of the asserted claims infringed. App., *infra*, 50a. The general verdict form submitted to the jury, however, did not differentiate between literal infringement and infringement by equivalents. *Id.* at 50a n.8. In a separate phase of the trial, the jury then awarded Cordis more than $271 million in damages against Medtronic. (The jury in the action against BSC also found infringement of the same patents and awarded more than $300 million in damages.)

The district court found that prosecution history estoppel precluded Cordis from asserting the doctrine of equivalents for either the "slots formed therein" or "substantially uniform thickness" limitations. App., *infra*, 59a; *id.* at 65a. On reconsideration, the court also granted Medtronic a conditional new trial on the "substantially uniform thickness" limitation on the ground that the jury might have improperly relied on the doctrine of equivalents in rendering its verdict. *Id.* at 150a.

The Federal Circuit reversed. App., *infra*, 1a-25a. First, the court of appeals disagreed with the district court's construction of the slots limitation along with the finding of argument-based estoppel. *Id.* at 6a-13a. The court of appeals acknowledged that to distinguish Medtronic's prior art Wiktor patent and obtain allowance of the rejected '984 patent claims, Cordis had asserted that the Wiktor stent lacked a "wall surface having a plurality of slots." *Id.* at 11a. The court also recognized that Cordis must have relinquished

something by that argument. *Id.* at 11a-12a. In the Federal Circuit's view, however, Cordis could have meant "either that coiled wire is not a wall surface or that the openings in the coil do not constitute slots." *Id.* at 12a. The court of appeals did not consider whether Medtronic's stents would have infringed if either of these potential disclaimers were given effect, however. Rather, having found that Cordis' representation to the PTO was "amenable to multiple reasonable interpretations," the Federal Circuit resolved all doubts in Cordis' favor by determining that Cordis' disclaimer did not constitute a clear and unambiguous surrender of *any* subject matter. *Ibid.* Consequently, the court of appeals gave the disclaimer no effect at all.

In addressing the thickness limitation, the Federal Circuit acknowledged Cordis' argument during the reexamination of the '762 patent that

> the Ersek device is not smooth and that "the wall thickness [of an Ersek model] 'varied at different points' and 'ranged from a minimum thickness of 0.0035 inches to a maximum thickness of 0.0045 inches.'"

App., *infra*, 14a-15a. The court of appeals nonetheless concluded that Cordis' reliance on this argument to distinguish Ersek did not constitute a clear and unmistakable disclaimer of walls varying in thickness by .001 inch or more. Accordingly, the Federal Circuit held that these representations neither limited the literal scope of the claim to walls with less than .001 inch variation in thickness, nor precluded application of the doctrine of equivalents to embrace stents with greater variations in wall thickness. The court of appeals consequently reversed both the summary judgment of no literal infringement and the judgment as a matter of law of no infringement by the doctrine of equivalents.

REASONS FOR GRANTING THE PETITION

THE FEDERAL CIRCUIT'S DECISION CONFLICTS WITH THIS COURT'S JURISPRUDENCE HOLDING PATENTEES TO THE CONSEQUENCES OF THEIR ACTIONS BEFORE THE PTO.

This Court has repeatedly emphasized that "competitors may rely on the prosecution history," *i.e.*, "the public record of the patent proceeding," in determining the scope of patent claims and the permissible range of equivalents embraced by those claims. *Festo*, 535 U.S. at 727; *see also, e.g.*, *Graham* v. *John Deere Co.*, 383 U.S. 1, 33 (1966). The characterizations of claims that a patentee presents while seeking to persuade the patent examiner that the proffered invention is new provide one of the most reliable tools for the public who must assess the practical limits of those claims.

Because patent claims confer property rights, "clarity" of claim scope "is essential to promote progress, because it enables efficient investment in innovation." *Festo*, 535 U.S. at 730-731. That policy of clear claim demarcation underlies the statutory command that patents "distinctly claim the subject matter" they propose to remove temporarily from the public domain. 35 U.S.C. § 112, ¶ 2.

Patent applicants' representations to preserve their claims against prior art challenges during prosecution also should be clearly stated. Although this Court's attention has focused more often on claim amendments than on other means of narrowing a claim before the patent examiner, the Court's concerns with the integrity of the patent application process and the reliability of the prosecution history are not confined to amendments. From the earliest days, the Court has examined what patent applicants have said on the public record as well as what they did. *See, e.g.*, *Goodyear Dental Vulcanite Co.* v. *Davis*, 102 U.S. (12 Otto) 222, 227-228 (1880); *Watson* v.

Cincinnati, I., St.L., & C. Ry., Co., 132 U.S. 161, 164-167 (1889). The full "history of the application for the patent as it passed through the patent-office" helps determine "the proper construction of the claims allowed." *Sargent* v. *Hall Safe & Lock Co.*, 114 U.S. 63, 73 (1885).

As this Court has recognized, to "hold the inventor to the representations made during the application process" (*Festo*, 535 U.S. at 737), *arguments* and *amendments* made by patentees during patent prosecution should be "strictly construed" against the patentee so that the patentee cannot recapture through litigation subject matter that it surrendered to obtain the patent. *MacKay Radio & Tel. Co.* v. *Radio Corp. of Am.*, 306 U.S. 86, 93-95 (1939). This is not merely a matter of convenience, but one of fundamental public policy underlying the patent laws, since what is "strictly construed against the inventor" is construed "in favor of the public." *Sargent*, 114 U.S. at 86.

In determining where presumptions drawn from the prosecution history should fall, and what circumstances should lead to categorical narrowing of the scope of patent protection, this Court has referred to the "delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights." *Festo*, 535 U.S. at 731. By according all presumptions to the patentees when interpreting arguments made during patent prosecution, the Federal Circuit has upset that balance. This Court's intervention is necessary to restore it.

A. The Federal Circuit's Resolution Of All Doubts In Favor Of The Patentee Conflicts With Decisions Of This Court That Strictly Construe Patentees' Statements And Actions Taken To Overcome Rejections By The PTO.

This Court has firmly held that a narrowing claim *amendment* creates a rebuttable presumption that prosecution history estoppel applies and that application of estoppel results in the surrender of equivalents to the narrowed claim. *See Festo*, 535 U.S. at 733-737. To preserve "both [the] definitional and [the] notice function" of the patent claims and the prosecution history, this Court placed the "burden *on the patent holder*" to establish the reason for an amendment required during patent prosecution. *Warner-Jenkinson*, 520 U.S. at 33 (emphasis added). The Court extended the burden in *Festo*, explaining that just as "the patentee bears the burden of proving that an amendment was not made for a reason that would give rise to estoppel," the patentee also "should bear the burden of showing that the amendment does not surrender the particular equivalent in question." *Festo*, 535 U.S. at 740. The Court explained that this rebuttable presumption "hold[s] the inventor to the representations made during the application process and *to the inferences that may reasonably be drawn* from the amendment." *Id.* at 737-38 (emphasis added). In other words, upon an initial showing that an amendment in some way narrowed the scope of a claim element, this Court resolves doubts *against the patentee*.

In contrast with this Court's admonition to "hold the inventor to the representations made during the application process," *Festo*, 535 U.S. at 737, the Federal Circuit resolves all doubts in the patentee's favor when considering the narrowing effect of *statements* made to the PTO expressly to overcome a prior art rejection. For purposes of prosecution disclaimer or of prosecution history estoppel, the Federal Circuit generally gives no effect to an argument made to overcome a rejection by the PTO unless the relinquishment

of subject matter is not only persuasive to the patent examiner, but also "clear and unmistakable" to a panel of appellate judges.[3] App., *infra*, 12a. The court of appeals treats a conclusory argument that could distinguish a claim element from prior art on several grounds as too "ambiguous" to be charged against the patentee, even if that argument overcame a rejection based on the same prior art. *Id.* at 15a. As a consequence, under the Federal Circuit's jurisprudence, a disclaimer susceptible to two reasonable inferences cannot limit the claim at all. And the Federal Circuit also gives no effect, for purposes of claim construction or prosecution history estoppel, to even a crystal-clear quantitative statement made to distinguish prior art, so long as the statement is joined with other distinctions. For practical purposes, the court of appeals gives patentees a free pass to make narrowing *arguments* to the patent examiner without fear of actually restricting the scope of the patent, so long as the arguments are sufficiently complex or unclear.

The absurd consequences of this jurisprudence are apparent in this case. In refusing to hold Cordis to the narrowing arguments made during prosecution of the '984 patent to distinguish the wire stent in the prior art Wiktor patent the Federal Circuit identified two separate disclaimers that reasonably could be inferred from the arguments. *See* App., *infra*, 12a. Under one reasonable interpretation, Cordis disclaimed the notion that a coiled wire stent was a "wall sur-

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[3] This unduly restrictive standard has supplanted earlier pre-*Festo* Federal Circuit authority finding that arguments "distinguishing the claimed invention over prior art" indicate what the claims do not cover and "by implication surrender[]" that scope, *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1304 (Fed. Cir. 1997), and resolving ambiguities against the patentee when a claim limitation is equally susceptible to a broad or narrow claim construction. *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996).

face." *Ibid.* Under another reasonable interpretation, Cordis disclaimed the notion that the "openings in the coil" were "slots." *Ibid.* Faced with this choice, the court of appeals declined to hold that *both* claim elements had been narrowed by disclaimer. Nor did the court consider whether *either* reasonably inferable disclaimer, considered separately, would suffice to render Medtronic's accused stents non-infringing; indeed, the court of appeals did not dispute that Medtronic would *not* infringe under either reasonable interpretation of Cordis' statement.

Rather, the court of appeals transformed Cordis' *successful* narrowing argument into a *nullity* for purposes of claim construction and argument-based prosecution history estoppel alike—rewarding rather than penalizing Cordis for its obfuscation before the PTO. In the Federal Circuit's view, a narrowing argument that is subject to "*multiple* reasonable interpretations" has no effect on the scope of the claims at all. *Ibid.* (emphasis added). That truly gives patentees the best of both worlds: maximum narrowing effect before the PTO in order to obtain the patent, and no narrowing at all in infringement litigation.

Similarly, in arguing to overcome a rejection for anticipation by the Ersek patent during re-examination of the '762 patent, Cordis pointed out several separate features of the Ersek wall surface that, Cordis argued, did not meet the "substantially uniform thickness" limitation. *See* App., *infra*, 14a-15a. As the Federal Circuit recognized, Cordis asserted that the Ersek walls were thicker at junction-points in the device than elsewhere. *Id.* at 15a. In addition, apparently recognizing that the examiner might find the rest of the wall surfaces to be of "*substantially* uniform thickness," Cordis specifically argued that the variation in thickness was from "0.0035 inches to * * * 0.0045 inches." *Ibid.*

If Cordis were willing to rely on the junction points to overcome the rejection, it would have had no reason to add

this concrete, quantitative illustration of what was *not* "substantially uniform" in its view. Indeed, a reasonable competitor reviewing the prosecution history could scarcely hope for a clearer statement of the limits of the "substantially uniform thickness" limitation. Yet the Federal Circuit gave Cordis a free pass on this argument as well, deciding that it was not as important as other arguments made on the same point. Yet if Cordis had not viewed the 0.001-inch variation as determinative, why did it bring that feature to the PTO's attention? The Federal Circuit, reading the prosecution history not at all like a competitor looking for concrete and specific evidence of the scope of the claims, gave the patentee the benefit of a rather slim doubt here as well.

By contrast, this Court has held that the patentee's amendments and statements made to distinguish prior art should be "strictly construed" in determining the literal scope of the claims. *See, e.g., MacKay Radio*, 306 U.S. at 93-95; *Weber Elec. Co. v. E. H. Freeman Elec. Co.*, 256 U.S. 668, 677-78 (1921). For example, in *MacKay*, this Court narrowly construed the claim limitation at issue based on the patentee's statements concerning that limitation and the prior art. 306 U.S. at 95. Likewise, in *Weber Electric*, this Court barred the patentee from recapturing through claim construction or the doctrine of equivalents subject matter that the patentee had surrendered through its amendments and arguments before the PTO. 256 U.S. at 677-78.

Just as *amendments* introduced to overcome a rejection "must be strictly construed against the inventor and in favor of the public, and looked upon as in the nature of disclaimers," *Sargent*, 114 U.S. at 86, so, too, must *statements* made in order to induce a patent examiner to retract a rejection. *Cf. Westinghouse* v. *Boyden Power Brake Co.*, 170 U.S. 537, 559-560 (1898) (reading in limitation to claim based on "correspondence" with Patent Office, as well as less germane amendments). As this Court has recognized, when a patent claim will bear a construction that accords with "what the

patentee said when he was making his application," it is "reasonable" to construe the claim in accord with the patentee's argument to the PTO. *Goodyear Dental*, 102 U.S. (12 Otto) at 227. The Federal Circuit's current doctrine, which construes all prosecution history statements in *favor* of the patentee both for claim construction and for application of the doctrine of equivalents, conflicts with this Court's emphasis on holding patent applicants responsible for their actions and statements in the public record of the patent application. *See Festo*, 535 U.S. at 726. The decision below therefore warrants further review.

B. The Federal Circuit's Decision Undermines The Public Notice Function Of The Prosecution History By Applying Inconsistent Standards For Determining Amendment-Based Estoppel, Argument-Based Estoppel And Prosecution Disclaimer.

The Federal Circuit currently applies inconsistent standards to amendments and arguments made during patent prosecution even though the two serve the same purpose: overcoming the prior art to obtain issuance of the patent. *Arguments* made expressly to avoid a rejection for prior art will neither limit the literal scope of the claim preserved in that way, nor preclude the application of the doctrine of equivalents, unless the patentee who succeeded in persuading the PTO that the claim was narrower than it seemed also disclaimed each particular feature identified to the PTO with unmistakable clarity. Yet narrowing claim *amendments* — even wholly unexplained ones — are subject to sweeping prosecution history estoppel unless the amendment meets one of the difficult standards identified by this Court for rebutting the presumption of estoppel. *See Festo*, 535 U.S. at 740-41.

This inconsistency heightens the need for further review because it makes no sense and undermines the public notice

function of the prosecution history. "The public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent." *Springs Window Fashions LP* v. *Novo Indus.*, 323 F.3d 989, 995 (Fed. Cir. 2003). Just as a "patent holder should know what he owns, * * * the public should know what he does not." *Festo*, 535 U.S. at 731. Under the current inconsistent standards, no one knows what has been disclaimed and what has not.

The notice function of the prosecution history is especially important because each patent grant takes a sphere of invention temporarily out of the public domain. The broader the patent claim construction, the less room for independent invention — and for the consumer benefits of competition.

Strict construction of the scope of patent claims in light of the patentee's arguments to the patent examiner preserves the "delicate balance" between adequate protection for true innovators and adequate protection of the public interest in competition. *See Festo*, 535 U.S. at 731. Claims themselves must be "distinctly" expressed in order to justify excluding the public from an invention. 35 U.S.C. § 112, ¶ 2. Thus, where a claim term is equally susceptible to two meanings, "the notice function of the claim [is] best served by adopting the narrower meaning." *Athletic Alternatives, Inc.* v. *Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996). That is especially true when a narrowing argument bolsters the narrower meaning. *See Goodyear Dental*, 102 U.S. (12 Otto) at 227.

The public notice function of the prosecution file underlies the presumption of estoppel that arises with narrowing claim *amendments*, since the public should not have to guess at what the patentee surrendered through amendment. Such guesswork is no more appropriate when narrowing *representations* made during patent prosecution are at issue. The rationale for resolving ambiguities against the patentee applies with equal force to the doctrines of argument-based estoppel

and prosecution disclaimer. The patentee has full control over the clarity of arguments made during prosecution. Just as an amendment "recognize[s] and emphasize[s] the difference" between the original phrase and the narrower amended one, *Festo*, 535 U.S. at 734 (quoting *Exhibit Supply Co.* v. *Ace Patents Corp.*, 315 U.S. 126, 136-137 (1942)), a narrowing argument "recognize[s] and emphasize[s]" the need for a narrowing construction of a given phrase. The public certainly should be able to rely on the patentee's arguments — explicitly made to distinguish prior art — as much as on amendments made for unknown reasons.

The Federal Circuit's willingness to relieve a patentee from the restrictive implications of an argument that helped forestall or overcome a rejection "undercut[s] the public's reliance on a statement that was in the public record and upon which reasonable competitors formed their business strategies." *Hockerson-Halberstadt, Inc.* v. *Avia Group Int'l, Inc.*, 222 F.3d 951, 957 (Fed. Cir. 2000). Under the Federal Circuit's approach, the public can never know whether a court will later find that, while the patentee's statements were clear enough to have the desired effect on the examiner, they were not sufficiently "clear and unmistakable" to surrender the subject matter that the examiner believed had been disclaimed.

The Federal Circuit's skewed vision of public notice removes all risk from patent applicants' assertions to the PTO. While the Federal Circuit claims that it is "balanc[ing] the importance of public notice and the right of patentees to seek broad patent coverage" by "consistently" refusing to give disclaimer or estoppel effect to "prosecution statements too vague or ambiguous to qualify as a disavowal of claim scope," *Omega Eng'g, Inc.* v. *Raytek Corp.*, 334 F.3d 1314, 1325 (Fed. Cir. 2003), the standard of unmistakable clarity tips the balance well toward the patentee and away from public notice. Indeed, the unmistakable clarity standard renders much of the prosecution history meaningless, even when

from all indications the patent examiner was persuaded by the same arguments that are later deemed ineffectual for purposes of prosecution disclaimer and argument-based prosecution history estoppel.

A standard of *reasonable* clarity, with doubts resolved *against* the patentee, is the only rule consistent with *Festo* and better upholds the notice function of the claims, because it holds patentees to reasonable inferences arising from their statements and actions. Courts must interpret the specification and claims from the perspective of a "person skilled in the art." 35 U.S.C. § 112, ¶ 1. Representations made to the PTO about a claim likewise should be evaluated from the same perspective of a person reasonably skilled in the relevant art, since the intended audience for the prosecution history should be the same as the intended audience for the patent claims. Those persons — competitors — should be able to rely on the very statements that the patentee proffered to win acceptance of the patent claims.

C. The Federal Circuit's Decision Creates Perverse Incentives for Patentees To Muddle The Prosecution Record And To Engage In Gamesmanship Before The PTO.

The Federal Circuit's heavy presumption against prosecution disclaimer and argument-based estoppel not only undermines the notice function of the prosecution history, but also promotes the use of purposefully ambiguous arguments during patent prosecution. In direct conflict with policies announced by this Court, the Federal Circuit has sketched out a road map that allows inventors to "avoid the PTO's gatekeeping role and seek to recapture in an infringement action the very subject matter surrendered as a condition of receiving the patent." *Festo*, 535 U.S. at 734.

This Court's application of rebuttable presumptions against the patentee in the *amendment* context places the responsibility for a clear prosecution record where it belongs: with the patent applicant who alone has the ability to clarify the record before the PTO. A similar presumption resolving against the patentee any ambiguities in its *arguments* to the PTO likewise promotes a clear prosecution record.

By contrast, the Federal Circuit's holding creates perverse incentives, rewarding patentees who obscure the meaning of their claims to escape rejection, while penalizing those who clearly state their position or submit straightforward amendments. That regime encourages sophisticated gamesmanship: patentees will attempt to craft arguments and concessions that are clear enough to obtain issuance of the patent, but ambiguous enough, under the test announced in this case, to avoid any narrowing of the claims in litigation.

This reward for obfuscation also impairs the ability of patent examiners to rely on an applicant's representations regarding the scope and meaning of claim limitations, because they can no longer be certain that the patentee's representations will be given effect after the patent issues. Just as this Court rejected the notion that "a claim in a patent is like a nose of wax which may be turned and twisted in any direction," *White v. Dunbar,* 119 U.S. 47, 51 (1886), so an argument made to advance the prosecution of the patent should not become a "nose of wax" that can benefit the patentee by convincing the examiner that a claim is sufficiently narrow, but cannot harm the patentee by enforcing the same narrow scope in an infringement action.

D. The Scope Of Prosecution Disclaimer And Argument-Based Estoppel Present Exceptionally Important And Recurring Issues.

The issues presented here are undeniably important and recurring; indeed, they may arise in virtually every patent infringement action. Whenever a patent examiner rejects —

or even expresses doubt over — a claim in a patent application, the applicant must respond in some way. Sometimes, of course, the applicant capitulates to the examiner's concerns by simply amending the claims, giving rise to the amendment-based prosecution history estoppel that the Court has twice addressed in recent years in *Festo* and *Warner-Jenkinson*. As often, however, the applicant preserves the claim terms without amendment, instead using a disclaimer or other argument to persuade the patent examiner that the claims do not read upon the prior art that had raised the examiner's doubts. Statements of that kind come into play in almost *every* exercise in claim construction in a patent infringement case, and often affect as well the scope of equivalents that may be covered by the claim. It thus is unsurprising that recent published cases reflect the recurrent questions over the application of both prosecution disclaimer and argument-based prosecution history estoppel to the PTO records.[4]

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[4] In addition to the decision below, recent published decisions addressing prosecution disclaimer during 2003 alone include *3M Innovative Props. Co.* v. *Avery Dennison Corp.*, 350 F.3d 1365, 1373 (Fed. Cir. 2003); *ACCO Brands, Inc.* v *Micro Sec. Devices, Inc.*, 346 F.3d 1075, 1078-1079 (Fed. Cir. 2003); *Arlington Indus., Inc.* v. *Bridgeport Fittings, Inc.*, 345 F.3d 1318, 1327-1330 (Fed. Cir. 2003); *Sunrace Roots Enter. Co., Ltd.* v. *SRAM Corp.*, 336 F.3d 1298, 1306-1308 (Fed. Cir. 2003); *Omega Eng'g, Inc.* v. *Raytek Corp.*, 334 F.3d 1314, 1323-1327 (Fed. Cir. 2003); *Invitrogen Corp.* v. *Biocrest Mfg., L.P.*, 327 F.3d 1364, 1367-1370 (Fed. Cir. 2003); *Springs Window Fashions LP v. Novo Indus.*, 323 F.3d 989, 994-996 (Fed. Cir. 2003); *Pandrol USA, LP* v. *Airboss Ry. Prods., Inc.*, 320 F.3d 1354, 1363-1364 (Fed. Cir. 2003); *Rambus Inc.* v. *Infineon Techs. AG*, 318 F.3d 1081, 1094-1095 (Fed. Cir. 2003); *Oakley, Inc.* v. *Sunglass Hut Int'l*, 316 F.3d 1331, 1344-1345 (Fed. Cir. 2003).

Recent published appellate decisions addressing argument-based estoppel include *Deering Precision Instruments, L.L.C.* v.

If patentees are not held to the reasonable consequences of their statements, research and innovation will suffer. Researchers and innovators necessarily must assume the risk that their time, money and human resources may not yield a commercially viable product. But it surely does not "promote the Progress of Science and useful Arts" (U.S. Const., art. I, § 8) to require innovators to assume the additional risk that a court will subsequently interpret an old patent to cover a new product even though that product was reasonably encompassed by the patentee's own disclaiming statements in the file history.

The medical device industry involved in the present case — like the pharmaceutical, computer, chemical, and many other industries of critical importance to the economy — is rapidly changing and heavily dependent on research. Corporations commit huge sums of money to make improvements that save and prolong lives, and improve the quality of life for millions of people. That dynamic cannot continue if patentees are permitted to play fast and loose with their statements to the PTO. This Court's prompt intervention is necessary.

Vector Distribution Sys., 347 F.3d 1314, 1326 (Fed. Cir. 2003); *Storage Tech. Corp.* v. *Cisco Sys., Inc.*, 329 F.3d 823, 836 (Fed. Cir. 2003); *Schwing GmbH* v. *Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1326-1327 (Fed. Cir. 2002); *Eagle Comtronics, Inc.* v. *Arrow Communication Labs., Inc.*, 305 F.3d 1303, 1316 (Fed.Cir.2002); *Allen Eng'g Corp.* v. *Bartell Indus., Inc.*, 299 F.3d 1336, 1350 (Fed. Cir. 2002); *Interactive Pictures Corp.* v. *Infinite Pictures, Inc.*, 274 F.3d 1371, 1378-1380 (Fed. Cir. 2001).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

02-1457, -1458, -1481, -1482

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CORDIS CORPORATION,
Plaintiff-Appellant,

v.

MEDTRONIC AVE, INC.,
Defendant-Cross Appellant,
and
BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,
Defendants.

MEDTRONIC AVE, INC.,
Plaintiff-Cross Appellant,
and
ARTERIAL VASCULAR ENGINEERING, INC.,
Counterclaim Defendant-Appellee,

v.

CORDIS CORPORATION,
Defendant/Counterclaimant-Appellant,
and
JOHNSON AND JOHNSON and EXPANDABLE GRAFTS PARTNERSHIP,
Defendants.

DECIDED: August 12, 2003

JUDGES: Before NEWMAN, BRYSON, and GAJARSA, Circuit Judges.

BRYSON, Circuit Judge.

Cordis Corporation appeals from a final judgment of the United States District Court for the District of Delaware. Cordis seeks review of (1) a summary judgment that defendant Medtronic AVE., Inc., ("AVE") did not literally infringe two of Cordis's patents, and (2) a judgment as a matter of law ("JMOL") that AVE did not infringe those patents under the doctrine of equivalents. Because we disagree with the district court's claim construction and its application of prosecution history estoppel, we reverse the judgment and remand for further proceedings.

I. Background

The development of balloon-expandable coronary stents marked a significant advance in the treatment of coronary artery disease by providing an alternative to balloon angioplasty and bypass surgery. In balloon angioplasty, an inflated balloon crushes built-up plaque against the arterial wall to improve blood flow. The balloon is withdrawn at the end of the procedure, however, which allows the artery to close again over time. A stent of the sort disclosed in the patents at issue in this case is mounted on an angioplasty balloon and is forced to expand against the arterial walls when the balloon is inflated. When the balloon is deflated and withdrawn, the stent retains its shape and remains in the artery to keep it open. Because the stent's diameter depends on how much the balloon expands, the stent can be used in arteries of differing diameters. Prior art

stents that were designed to remain in arteries had predetermined expanded diameters. Accordingly, they were liable to migrate from the desired location if they were too small or to rupture the artery if they were too large.

A

The two patents at issue in this case are owned by Cordis. U.S. Patent No. 4,739,762 ("the '762 patent") discloses an expandable stent composed of a tubular member having a wall surface of substantially uniform thickness with "a plurality of slots formed therein" parallel to the longitudinal axis of the tubular member. After the stent is transported in its unexpanded form to the intended location within the patient's body, an outwardly directed radial force (as by the inflation of the balloon) causes the stent to expand. The stent can be expanded and deformed according to the diameter of the body passageway in which it is located. See '762 patent, col. 3, ll. 33-51. Certain claims of the '762 patent specify that the tubular member is "thin-walled" and "smooth."

Approximately ten years after issuing the '762 patent, the PTO reexamined the patent in light of several prior art references. During the reexamination, the examiner rejected several claims in view of, inter alia, U.S. patents to Ersek and to Kornberg. The Ersek patent claims a fixation device with projecting edges that can be used as a substitute for sutures; the device serves to hold a prosthesis in place within a body passageway. Ersek recites that his device is preferably formed from expanded metal sheeting and is produced by forming a series of staggered parallel slits in a metal sheet and then stretching the sheet in a direction perpendicular to the slits to open the slits into apertures. The

resulting projecting edges embed themselves into the tissue wall upon expansion of the sleeve.

In response to the examiner's rejection, Cordis amended various claims of the '762 patent to include the "substantially uniform thickness" limitation that was already present in claim 23. Cordis argued that the limitation distinguished its patent from the Ersek patent, noting that "[t]he expanded metal Ersek sleeve has bridge portions that are several times as thick as the strands." In its discussion of the Ersek patent, Cordis relied in part on an affidavit of Dr. Erik Antonsson that addressed the dimensions of a model of the Ersek device. Cordis also distinguished the Ersek patent based on its contention that Ersek did not disclose either a "smooth" surface or a "thin-walled" tubular member. The examiner then confirmed the claims of the '762 patent that are asserted in this case. The examiner distinguished the Ersek patent on the ground that the Ersek sleeve is not smooth because "the bridge has a thickness which is twice as great as the strand."

The other Cordis patent at issue in this case is U.S. Patent No. 5,195,984 ("the '984 patent"). That patent adds the feature of flexibility by including a connector member to link one tubular member of the stent to another. The written description provides that the claimed device, with its connector member, "permits tissue of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in tortuous body passageways, such as the vascular system." '984 patent, col. 4, ll. 20-25. The examiner initially rejected claims of the '984 patent as anticipated by or obvious in light of a U.S. patent to Wiktor. After the applicant distinguished the Wiktor patent, the examiner allowed the claims without amendment. The '984

patent is unrelated to the '762 patent, but the written descriptions of the two are very similar.

B

Cordis filed suit, charging AVE and others with patent infringement. AVE produces stents that are formed by first bending wire rings into a sinusoidal shapes and then connecting the bent rings together, as shown below.

Cordis alleged, inter alia, that AVE's stents infringe claims 23, 51, and 54 of the '762 patent and claims 1 and 3 of the '984 patent. All of the asserted claims recite a "wall surface having a substantially uniform thickness and a plurality of slots formed therein."

The district court construed the claim language referring to a "plurality of slots formed [in the wall surface]" to be limited to devices in which the slots are formed by the removal of material. No material is removed from a pre-existing wall to form the slots in AVE's accused stents; rather, the slots are formed when wire-like material is bent into sinusoidal rings, which are then connected in line. Because the court concluded that the accused products did not satisfy the "plurality of slots formed therein" limitation, the court granted AVE's motion for summary judgment of no literal infringement.

The district court construed the reference to a "wall surface having a substantially uniform thickness" to mean that the thickness of the wall may not vary by more than 0.001 inch. The court reached that conclusion based on the patentee's citation, during reexamination, of the Antonsson affidavit, which reported that the wall of a device modeled on the Ersek patent was between 0.0035 inches and 0.0045 inches in thickness.

After a two-week trial, a jury found that AVE's stents infringed the asserted claims of the '762 and '984 patents under the doctrine of equivalents and awarded Cordis $271 million in damages. On post-trial motions, however, the district court granted JMOL of noninfringement, holding that Cordis was barred from asserting that AVE's stents had features that were equivalent to the "plurality of slots formed therein" and "substantially uniform thickness" limitations. In addition, the court granted a conditional new trial with respect to literal infringement of the "substantially uniform thickness" limitation.

II. "A Plurality of Slots Formed Therein"

With regard to the grant of summary judgment of no literal infringement, the district court ruled that the phrase "slots formed therein" requires that the slots' be manufactured by removing material from a pre-existing wall surface. We disagree. Slots can be "formed" in a wall surface by means other than removing material, such as by constructing the wall with openings built into it.

Nothing about the phrase "slots formed therein" suggests that the slots must be formed by a particular

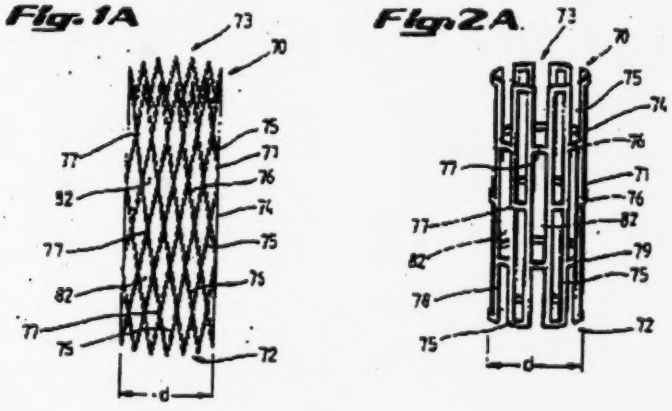
process; the phrase certainly does not indicate that the wall must be formed first and the slots formed later. A piece of wire mesh can fairly be described as a metal surface with holes formed in it, but that description does not mean that the screen was made, by starting with a solid piece of metal and drilling holes in it. The phrase "slots formed therein" describes the physical characteristics of the product, not the method of its manufacture.

We also reject AVE's contention that the '762 patent's definition of a slot as an "opening" indicates that the stent must be made by forming an opening in previously solid material. An opening can arise by leaving a gap during the construction of a wall surface as well as by removing material from the surface. Because the language "formed therein" does not require the removal of material as the method of formation, we decline to superimpose a process limitation on the product claims at issue. See Vanguard Prods. Corp. v. Parker Hannifin Corp., 234 F.3d 1370, 1372 (Fed. Cir. 2000) (holding that the limitation of a thin layer "integral therewith" described the product and did not designate a specific manufacturing process, and that a "method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process").

The specifications of the '762 and '984 patents do not define the "slots formed therein" as openings created by the removal of material from a pre-existing wall surface. AVE relies on the statement "[p]referably, tubular member 71 is initially a thin-walled stainless steel tube having a uniform thickness and a plurality of slots are formed in the wall surface 74 or tubular member 71." '762 patent, col. 6, ll. 41-44; '984 patent, col. 5, ll. 64-67. But the use of the term

"preferably" makes clear that the language describes a preferred embodiment, not the invention as a whole.

The district court based its holding that the "[s]lots must be formed in the wall surface of a tubular member, as by the removal of material" in part on the progression of the written description of the '762 patent from its parent, U.S. Patent No. 4,733,665 ("the '665 patent"). Specifically, the district court relied on the fact that one of the embodiments disclosed in the '665 patent was not carried over into the specification of the '762 patent application, which was filed as a continuation in part ("CIP"). The '665 patent discloses two differing embodiments, which are shown in Figures 1A and 2A:



The written description of the '665 patent states, "Preferably, tubular shaped member 71 [of Figure 1A] is made of continuous, stainless steel wire woven in a crisscrossed tubular pattern to form what can be generally described as a wire mesh tube." '665 patent, col. 6, ll. 49-52. Because the wire is criss-crossed, the tube is twice as thick at the cross points as at other points on the structure. That

embodiment is not present in the specification of the '762 patent or the '984 patent.

Like the district court, AVE relies on the absence of the Figure 1A embodiment from the '762 and '984 patents as indicating that Cordis disclaimed bent-wire stents lacking a pre-existing wall surface from which material is removed to create the slots. We reject this basis for narrowing the claims. In neither patent is there any language surrendering bent-wire stents, and the fact that the patentee chose not to include Figure 1A from the '665 patent as an embodiment in the '762 specification does not indicate that the patentee was no longer claiming any stent composed of bent wire. Rather, it is likely that the patentee chose not to include that embodiment because its overlapping members caused it not to be of substantially uniform thickness, smooth, or thin-walled (all features claimed in the '762 patent, but not in the '665 patent).

A patentee may choose not to carry forward a particular embodiment from a parent patent to a CIP because that embodiment does not satisfy a limitation that was added in the CIP. That choice, however, does not mean that the scope of the CIP is limited to the preferred embodiment that was carried forward. Thus, we reject AVE's contention that the failure to include a wire mesh embodiment in which wires have been bent and overlapped to form the stent should limit the construction of the claims to exclude all embodiments created by bending wire in any form.

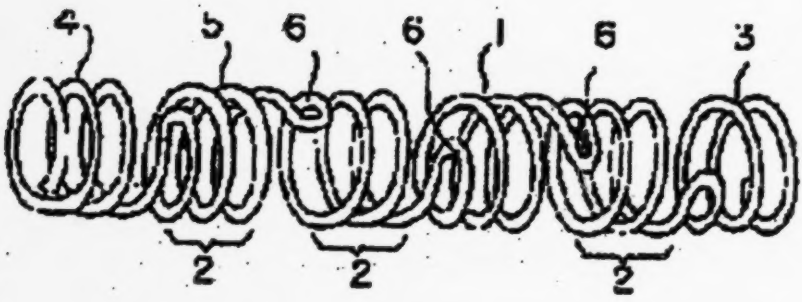
The district court compared the methods of making the preferred embodiments of the '665 patent and concluded that the difference between the Figure 1A and Figure 2A embodiments is that "the elongate bars of the 'thin bar'

[Figure 2A] embodiment 'maybe formed integral with one another,'" a method of manufacture that the district court found to be "singularly descriptive of the slotted tube preferred embodiment." However, expert testimony established that one of skill in the art would understand "formed integral with one another," in the context of the patents at issue, to refer to formation from a single piece of material, which does not require construction by removal of material from a pre-existing piece of metal.

We also disagree with the district court's conclusion that it is significant that the '665 patent claims a "plurality of intersecting elongate members" while the '762 patent claims a "wall surface having ... a plurality of slots." Claiming a wall having slots is essentially the same as defining a hole in terms of the structure that forms the hole.

We next consider statements made in the prosecution history of the '984 patent regarding the prior art Wiktor patent to determine whether the patentee effected a disclaimer of claim scope. Such a disclaimer requires clear and unmistakable statements of disavowal. See Omega Eng'g, Inc. v. Raytek Corp., Nos. 01-1546, 02-1478, slip. op. at 17 (Fed. Cir. July 7, 2003).

Dr. Schatz, the inventor of the '984 patent, characterized Wiktor as disclosing "a coiled wire stent which is a 'tubular shape of coiled wire wound in a special manner comprising a number of groups of turns 2.'" The coiled wire stent in Wiktor has openings spiraling around its circumference as shown, herein:



In response to the examiner's rejection of the application for the '984 patent in view of the Wiktor patent, Dr. Schatz stated:

> Wiktor does not disclose a plurality of "thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member". Wiktor discloses a single stent, or graft made up of coiled wire. There is no wall surface having a plurality of slots, nor slots disposed parallel to the longitudinal axis of each tubular member. Applicant's claimed invention is not "coiled wire wound in a special manner comprised of a number of groups of turns" as illustrated in Wiktor.

The first sentence of Dr. Schatz's statement about Wiktor is a general allegation that Wiktor does not disclose the precise combination of elements claimed in the '984 patent. That statement cannot be read to disclaim any device not containing a pre-existing wall from which material is

removed. Dr. Schatz more specifically distinguishes the Wiktor patent in his statement that "[t]here is no wall surface having a plurality of slots, nor slots disposed parallel to the longitudinal axis of each tubular member." Clearly, he is correct that Wiktor does not have slots disposed parallel to the longitudinal axis of the member; even if the openings in Wiktor do constitute slots, they are perpendicular to the longitudinal axis of the member. It is not clear, however, what Dr. Schatz meant by "no wall surface having a plurality of slots." He could have meant either that coiled wire is not a wall surface or that the openings in the coil do not constitute slots. The statement is amenable to multiple reasonable interpretations and it therefore does not constitute a clear and unmistakable surrender of all stents that lack a pre-existing wall surface from which material is removed to form the slots. In addition, the statement does not clearly disclaim any stents made of bent wire on the ground that a stent made of wire lacks any "wall surface," as AVE contends.

Rather than supporting a narrow construction of the "slots formed therein" limitation, the prosecution history of the '762 patent—and particularly the reexamination—indicates that the patentee did not intend for the phrase "slots formed therein" to require the removal of material. For example, the examiner, in discussing the Kornberg patent, stated that "Webster's Ninth New Collegiate Dictionary defines 'slot' as 'a narrow opening or groove.' The spaces between the Kornberg struts certainly meet this definition. The slots are formed in the tubular member since the struts are part of the wall of the tubular member." The examiner's remarks indicate that he understood that "slots formed therein" describes the location of the slots, not how they are made. The patentee did not dispute that statement by the examiner. The examiner also described the Ersek patent's device as having "a plurality of slots 23 formed therein"

even though Ersek's slots are not made by removing material. The patentee distinguished the Ersek patent, but did not dispute that Ersek's device has a plurality of slots formed therein. Accordingly, the patentee did not rely on the method of manufacturing as a means of distinguishing the invention from the prior art. Because the prosecution histories of the '762 and '984 patents do not support the narrow reading of the "slots formed therein" limitation, we conclude that the district court erred in construing the "slots formed therein" limitation in the two patents to require that the slots be formed by removing material from a pre-existing wall surface.

Because we disagree with the district court's construction of the "plurality of slots formed therein" limitation, we reverse the district court's grant of summary judgment of no literal infringement based on that limitation. For the same reason, we also reverse the district court's ruling on the doctrine of equivalents, which was based on the court's construction of that limitation.

III. "Substantially Uniform Thickness"

Cordis also challenges the district court's construction of the "substantially uniform thickness" limitation and the court's related ruling on prosecution history estoppel. We agree with Cordis that the court's claim construction was unduly narrow and that the court's estoppel ruling was erroneous. Accordingly, we reverse the court's order granting JMOL of noninfringement under the doctrine of equivalents and its grant of a conditional new trial on literal infringement as to that limitation.

A

The district court construed the "substantially uniform thickness" limitation to require that the thickness of the stent's wall surface not vary by 0.001 inch or more. Cordis contends that the district court erred by imposing the numerical restriction of 0.001 inch with respect to that limitation.

The patents do not set out any numerical standard by which to determine whether the thickness of the wall surface is "substantially uniform." The term "substantially," as used in this context, denotes approximation. See Epcon Gas Svs., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1031 (Fed. Cir. 2002). Thus, the walls must be of largely or approximately uniform thickness. Moreover, the written descriptions of the two patents state only that the expansion of the tubular member is uniform "along the length of tubular member 71" in part because of the uniform thickness of the wall surface, specifically pointing to the "same uniform thickness" of the connecting members 77, the elongate members 75, and members 78 and 79. '762 patent, col. 7, ll. -21-33; '984 patent, col. 6, ll. 47-54. Accordingly, the "substantially uniform" limitation also requires that the thickness of the wall surface be sufficiently uniform along its length and between members to allow uniform expansion of the stent. The question presented here is whether there is anything in the prosecution history of either patent that justifies giving the "substantially uniform thickness" limitation an even narrower construction.

In its discussion of the Ersek patent during reexamination of the '762 patent, Cordis argued that, according to the Antonsson affidavit, the Ersek device is not

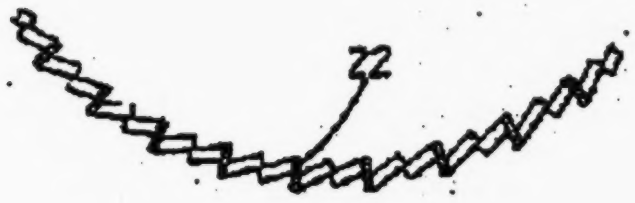
smooth and that "the wall thickness [of an Ersek model] 'varied at different points' and 'ranged from a minimum thickness of 0.0035 inches to a maximum thickness of 0.0045 inches.'" Cordis noted that the Antonsson affidavit addresses a model of an Ersek device in its expanded configuration, but that the thickness of the Ersek device is not substantially uniform in either its unexpanded or expanded configuration. Based on those statements, the district court construed the "substantially uniform thickness" limitation to require variations in wall surface thickness of less than 0.001 inch.

The commentary on Dr. Antonsson's measurement of a model, however, does not constitute a "clear and unmistakable" disclaimer, see Omega Eng'g, slip. op. at 17, excluding stents that vary in thickness by 0.001 inch or more. Cordis did not suggest that the variation of 0.001 inch was the basis for distinguishing its invention from Ersek or that Cordis's claimed stents vary by less than 0.001 inch in thickness. Rather, Cordis's basis for distinguishing Ersek appears to have been that Ersek's walls were at least twice as thick at the intersections of strands as along the strands themselves. The alleged disclaimer based on Dr. Antonsson's measurements in the reexamination proceedings was at best ambiguous. See IMS Tech., Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1439 (Fed. Cir. 2000) ("In light of the ambiguity of the patentee's statements and the subject matter actually disclosed in the references, we cannot say that the patentee clearly disavowed coverage of [the contested subject matter].").

In addressing Ersek, Cordis focused on the double thickness of the bridge portions of Ersek's walls. For example, in its response to the examiner's reexamination rejection of claims in light of Ersek, Cordis stated:

> As shown ... in Ersek Figure 5 ... the wall of [the Ersek device] is of varying thickness because the strands of the sleeve have twisted out of the plane of the starting material. Moreover, the bonds or bridges at the junctions of the strands protrude inwardly and outwardly of the plane of the starting material, and as a result the Ersek sleeve 16 has a non-uniform wall of varying thickness.
>
> Since the bonds or bridges extend generally radially outwardly of the sleeve 16, the sleeve has 100% variance in thickness as compared to the thickness of the starting material in the areas of the bonds or bridges.

Figure 5 of the Ersek patent is shown herein:



Cordis reiterated its contention that Ersek did not have a wall surface with a substantially uniform thickness in that submission:

> Clearly, the Ersek sleeve cannot be fairly said to have a wall surface with "a substantially uniform thickness". The expanded metal Ersek sleeve has bridge portions that are several times as thick as the strands. . . . The strands extending between the bridge portions

> are twisted to have inwardly and outwardly projecting edges. This irregular and variable configuration is rough and is the antithesis of "substantially uniform thickness". The use of the term "substantially uniform" does not exclude some variations in dimension between the inner and outer surfaces of the wall. Even so, it is clear that Ersek's rough and irregular wall does not have substantially uniform thickness. Antonsson Affidavit, paragraph 10.

At Cordis's request, Dr. George Andros submitted a declaration to the PTO as a part of the reexamination of the '762 patent. Dr. Andros stated that "[t]he Ersek fixation sleeve does not have a substantially uniform wall thickness, nor is it thin walled. The expanded metal sleeve is twice as thick in some areas as in others, and the thickness of the wall varies throughout." Cordis thus focused on the double thickness of the bridge portions of the Ersek device, not on Dr. Antonsson's assertion that the thickness of the Ersek device varied by up to 0.001 inch along the strands.

Based on our review of the prosecution history, we conclude that a reasonable reading of the patentee's statements would not lead one to conclude that variations greater than 0.001 inch fall outside the scope of the '762 patent. Because there is no clear and unmistakable disclaimer of any variation in thickness of 0.001 inch or more, the district court erred in imposing that numerical restriction on the "substantially uniform thickness" limitation. The discussion of the Ersek patent does, however, support the conclusion that the owner of the '762 patent disclaimed coverage of any device with a variation of at least 100 percent. In any event, quite apart from any disclaimer, a wall that varies in thickness by as much as 100

percent cannot be said to be of "substantially uniform thickness" either literally or by equivalents.

B

AVE contends that, under either party's construction, its stents have a variable thickness because they have a round or ellipto-rectangular cross-section and thus do not infringe because the cross-sectional thickness of its stent walls varies by more than 100 percent. We disagree and conclude that a stent formed from struts with circular or ellipto-rectangular cross-sections can have a wall of substantially uniform thickness.

First, both AVE's and Cordis's experts agreed that persons of ordinary skill in the art equate thickness with diameter in the case of round struts. Second, according to the patents' claims, it is the wall surface that needs to have a uniform thickness, and the full circumference of the round strut is not involved in making up the wall surface. The district court described the wall surface by stating that "[t]he outer surface of the tubular member must be disposed in a common cylindrical plane." That common "cylindrical plane" is formed by an imaginary circle that intersects with the outermost point of each round strut. The thickness of the wall is equal to the diameter of each round strut, i.e., the distance between the outer point that intersects the wall surface and the corresponding inner point that intersects a similar imaginary cylindrical surface on the inside of the tubular member. Thus, a stent with round struts can have a substantially uniform thickness as long as the round struts have substantially the same diameter.

We recognize that the '762 patent specifically references struts with a rectangular or square cross-section, '762 patent, col. 7, ll. 34-41, and that the '984 patent states that the cross-section of the struts may be "square, rectangular, or other," '984 patent, col. 6, ll. 58-63. That description, however, does not exclude circular or ellipto-rectangular struts, which would also facilitate uniform expansion of the stents.

C

The court concluded that allowing equivalents for the "substantially uniform thickness" limitation would vitiate the 0.001 inch variation requirement adopted by the court. Because we have rejected the 0.001 inch variation requirement, we reject that ground of the district court's doctrine of equivalents ruling.

AVE argues on appeal that the citation to the Antonsson affidavit during reexamination of the '762 patent created an argument-based estoppel. We reject AVE's argument to preclude infringement of the limitation through an equivalent. To invoke argument-based estoppel, the prosecution history must evince a "clear and unmistakable surrender of subject matter." Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449, 1458 (Fed. Cir. 1998). Just as the Antonsson affidavit failed to serve as a clear and unmistakable disclaimer in the claim construction analysis, it also fails to serve as a clear and unmistakable surrender of anything greater than 0.001 inch to bar coverage through the doctrine of equivalents. We have noted that the prosecution disclaimer standard "is the same standard applicable, in the context of doctrine of equivalents, to the doctrine of argument-based estoppel . . . and that our precedent has

recognized a relation between the doctrines of argument-based estoppel and prosecution disclaimer." Omega Eng'g, slip op. at 17 n.1.

IV. "Substantially Parallel" Connector Members

AVE offers another basis for upholding the grant of JMOL with respect to the '984 patent, arguing that the connector members in the accused devices are not disposed in a "substantially parallel relationship with respect to the longitudinal axis of the tubular members," as required by the claims of the '984 patent. For a connector member to be "substantially parallel" to the tubular members, the district court stated, the connector member "must run in substantially the same direction as the longitudinal axis of the adjacent tubular members. . . . This means 'that the slots and the connectors run in the same direction and are substantially aligned with one another.'" AVE contends that its connector members are perpendicular to the tubular members. In making that argument, AVE focuses on the relative width and length of its connector members to establish the direction in which the members lie.

Substantial evidence supports the jury's conclusion that the limitation as construed is satisfied in the accused devices. In AVE's stents, a connector member is found at the area where each sinusoidal ring is attached to the next sinusoidal ring. The span of the member along the longitudinal axis of the tubular members of the stent is shorter than the span perpendicular to that axis. Cordis's expert, however, explained that in determining how the connector members are disposed, one should look at what elements are being connected and draw a line between them to see where the relevant axis is. The expert testified that the

shape of the connector member is not important and that it does not matter which dimension of the connector member is longer. What is significant, he stated, is the axis along which the member connects the stent elements. He testified that "the connector member must be in alignment with the slots so it's connecting the slots together in a longitudinal arrangement," and he explained that the connector member in the accused devices satisfied that requirement. The jury was entitled to credit that testimony and to conclude that AVE's connector members are aligned with the adjacent slots, both of which are substantially parallel to the longitudinal axis of the tubular members.

V. Validity

The district court denied AVE's motion for JMOL as to the validity of the two patents in suit. The court rejected AVE's motion regarding the '762 patent on the merits and held that AVE had not raised its validity defense with respect to the '984 patent. AVE cross-appeals the district court's judgment on the issue of validity with respect to both patents. AVE has not demonstrated, however, that the district court erred in concluding that AVE raised its validity defense only with respect to the '762 patent. Accordingly, we address the invalidity argument only as it applies to the '762 patent.

The district court declined to overturn the jury's verdict that the written description of the '762 patent supports the construction of the term "plurality of slots" employed by the district court. AVE argues that the patent must be declared invalid because the district court's construction of "plurality of slots" to include tubular members composed solely of "half-slots" (slots bounded on

three sides by the wall surface) rendered the asserted claims invalid for lack of a written description. AVE contends that the written description supports only a construction that requires both "complete slots" (slots bounded on all four sides) and half-slots, with the half-slots located only at the ends of each tubular member. The district court, however, did not restrict the "plurality of slots" limitation to half slots or complete slots, or any combination of the two.

Paragraph 1 of section 112 of the Patent Act provides that the "specification shall contain a written description of the invention." To fulfill the written description requirement, the patent specification must describe an invention in sufficient detail that one skilled in the art can clearly conclude that the inventor invented what is claimed. Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997); In re Gosteli, 872 F.2d 1008, 1012 (Fed. Cir. 1989). The disclosure as originally filed does not, however, have to provide in haec verba support for the claimed subject matter at issue. See Fujikawa v. Wattanasin, 93 F.3d 1559, 1570 (Fed. Cir. 1996).

This court will reverse a denial of JMOL only "if the jury's factual findings are not supported by substantial evidence or if the legal conclusions implied from the jury's verdict cannot in law be supported by those findings." Door-Master Corp. v. Yorktowne, Inc., 256 F.3d 1308, 1312 (Fed. Cir. 2001). The burden at trial was on AVE to establish by clear and convincing evidence that the written description requirement was not met, in light of the presumption of validity; whether the written description requirement has been satisfied is a question of fact that is reviewed for substantial evidence when resolved by a jury. Abbott Labs. v. Syntron Bioresearch, Inc., Nos. 02-1203, 02-1257, slip.

op. at 20-21 (Fed. Cir. July 10, 2003); see also Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158 (Fed. Cir. 1998).

We conclude that the record supports a finding that AVE failed to prove that the written description requirement was not satisfied in this case. The term "slot" is explicitly defined in the specification of the '762 patent as "an opening whose length is substantially greater than its width." '762 patent, col. 7, ll. 17-19. In describing the preferred embodiment, the term "slot" is used to describe both openings that are fully bounded and those that are bounded on only three sides. For example, the written description recites, "Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, such half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71." '762 patent, col. 7, ll. 7-13; '984 patent, col. 6, ll. 30-36 (emphasis added). Both half-slots and complete slots are labeled as 82 and are described at times simply as "slots"; that term thus encompasses both types of openings. The claim does not limit the order or mixture of the slots. The term "plurality of slots" simply means multiple slots, not multiple kinds of slots.

It is true that the preferred embodiment detailed in the written description contains alternating complete and half-slots at the ends of the tubular members. As our case law makes clear, however, "[a]n applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344 (Fed. Cir. 2001). "A specification may, within the meaning of 35 U.S.C. § 112 para. 1, contain a written description of a broadly claimed

invention without describing all species that [the] claim encompasses." Utter v. Hiraga, 845 F.2d 993, 998 (Fed. Cir. 1988).

This case is thus analogous to Lampi Corp. v. American Power Products, Inc., 228 F.3d 1365, 1378 (Fed. Cir. 2000), in which we upheld the district court's conclusion that the written description was sufficient to support half-shells that are not identical when the patent drawings only showed identical half-shells. We stated that "[i]t is a familiar principle of patent law that a claim need not be limited to a preferred embodiment" and that the "drawings in the patent are merely a 'practical example' of the invention." Id.

AVE cites Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1998), to support its cross-appeal. In Gentry Gallery, we concluded that the written description requirement was not satisfied because while "the original disclosure clearly identifies the console as the only possible location for the controls," the claims did not limit the location of the control to the console. Id. at 1479. Gentry Gallery thus applied the "proposition that a broad claim is invalid when the entirety of the specification clearly indicates that the invention is of a much narrower scope." Cooper Cameron Corp. v. Kvaerner Oilfield Prod., Inc., 291 F.3d 1317, 1323 (Fed. Cir. 2002). In the present case, the entirety of the specification does not reflect that the invention goes to the narrower scope of a mixture of half and complete slots. Such a mixture was not conveyed as critical to the invention nor was it described as the only feasible design in the disclosure. Rather, as in Johnson Worldwide Associates, Inc. v. Zebco Corp., 175 F.3d 985, 993 (Fed. Cir. 1999), "the patent disclosure provides ample support for the breadth of the term [ ]; it does not 'unambiguously limit[ ]' the meaning of [the term]" to the narrower embodiment.

In this case, substantial evidence supports a finding that AVE failed to prove by clear and convincing evidence that the claims are invalid for failure to satisfy the written description requirement. We therefore sustain the judgment that the asserted claims of the '762 and '984 patents are not invalid under 35 U.S.C. § 112, para. 1 and affirm the denial of JMOL on that issue.

REVERSED AND REMANDED.

02-1457, -1458, -1481, -1482

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CORDIS CORPORATION,

Plaintiff-Appellant,

v.

MEDTRONIC AVE, INC.,

Defendant-Cross Appellant,

and

BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,

Defendants.

MEDTRONIC AVE, INC.,

Plaintiff-Cross Appellant,

and

ARTERIAL VASCULAR ENGINEERING, INC.,
Counterclaim Defendant-Appellee,

v.

CORDIS CORPORATION,

Defendant/Counterclaimant-Appellant,

and

JOHNSON AND JOHNSON and EXPANDABLE GRAFTS PARTNERSHIP,

Defendants.

JUDGMENT

Appeals from the United States District Court for Delaware in consolidated cases 97-CV-550, 97-CV-700, and 98-CV-65, Judge Sue L. Robinson.

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

REVERSED and REMANDED

ENTERED BY ORDER OF THE COURT

DATED: AUG 12 2003

ISSUED AS A MANDATE: October 10, 2003

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civil Action No. 97-550-SLR (consolidated)

CORDIS CORPORATION,
Plaintiff,

v.

MEDTRONIC AVE, INC., BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,
Defendants.

Civil Action No. 97-700-SLR

MEDTRONIC AVE, INC.,
Plaintiff,

v.

CORDIS CORPORATION, JOHNSON & JOHNSON and EXPANDABLE GRAFTS PARTNERSHIP,
Defendants.

Civil Action No. 98-19-SLR

BOSTON SCIENTIFIC CORPORATION,
Plaintiff,

v.

ETHICON, INC., CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,
Defendants.

Civil Action No. 98-197-SLR

CORDIS CORPORATION,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,
Defendants.

OPINION

Dated: March 28, 2002
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

Plaintiffs Expandable Grafts Partnership and Cordis Corporation, a division of Johnson & Johnson (collectively, "Cordis"), originally filed this patent infringement action on October 3, 1997 against defendants Medtronic AVE, Inc., Boston Scientific Corporation and Scimed Life Systems, Inc.[1] Cordis alleges that AVE infringed certain claims of

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[1] Defendant Medtronic AVE, Inc. will be referred to as "AVE." Defendants Boston Scientific Corporation and Scimed Life Systems, Inc.

United States Patent Nos. 4,739,762 (the "'762 patent") and 5,195,984 (the "'984 patent"). Cordis accuses BSC of infringing certain claims of the '762 patent and United States Patent Nos. 5,902,332 (the "'332 patent"), 5,643,312 (the "'312 patent"), and 5,879,370 (the "'370 patent"). The court held a seven-week bifurcated jury trial on the issues of infringement and invalidity, and a four-day bench trial on the issue of unenforceability. Currently before the court are the parties' motions for judgment as a matter of law and a new trial, and proposed findings of fact and conclusions of law regarding inequitable conduct.

II. BACKGROUND

A. The Technology

The dispute relates to balloon expandable stents. Balloon expandable stents and other types of stents are used to treat diseased blood vessels in the heart ("coronary arteries") and in other areas of the body ("peripheral arteries"). Coronary artery disease is caused by the buildup of fatty deposits on the inner lining of the coronary arteries. Known as atherosclerosis, this buildup narrows coronary arteries and may eventually block the flow of blood to the heart. Untreated coronary disease can have serious consequences, including angina, heart attack or even death. Similar narrowing in arteries away from the heart causes problems for people with peripheral artery disease.

Until about twenty-five years ago, the primary treatment for coronary lesions was medication or coronary artery bypass graft surgery. In approximately 1975, physicians began to use a non-surgical treatment called

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will be referred to collectively as "BSC." Advanced Cardiovascular Systems, Inc. ("ACS") was originally a defendant, but entered into a stipulated order of dismissal with Cordis prior to trial. (D.I. 705)

percutaneous transluminal coronary angioplasty, commonly known as "balloon angioplasty." During this procedure, a balloon attached to a wire catheter is snaked through a diseased artery until it reaches the site of blockage. A physician inflates the balloon, which compresses the fatty deposits against the vessel wall to open the artery and restore blood flow. The balloon and catheter are then removed from the body. Although balloon angioplasty represented a major advancement in combating artery disease, blood vessels often closed again within several months of the procedure. This recurrence of blockage is called "restenosis."

A stent improves the success of balloon angioplasty by minimizing the occurrence of restenosis. A stent is a small device that holds open an artery just like scaffolding inside a tunnel keeps the tunnel from collapsing. At issue in this case are balloon expandable stents which are used in conjunction with angioplasty balloons. The stent is placed on a balloon and inserted into an artery via a catheter. Once the balloon is at the area of blockage, it is inflated, which causes the stent to expand and press against the vessel wall, thereby opening the artery. The balloon is then deflated and removed, leaving the expanded stent in the artery to keep the vessel open and allow blood to flow.

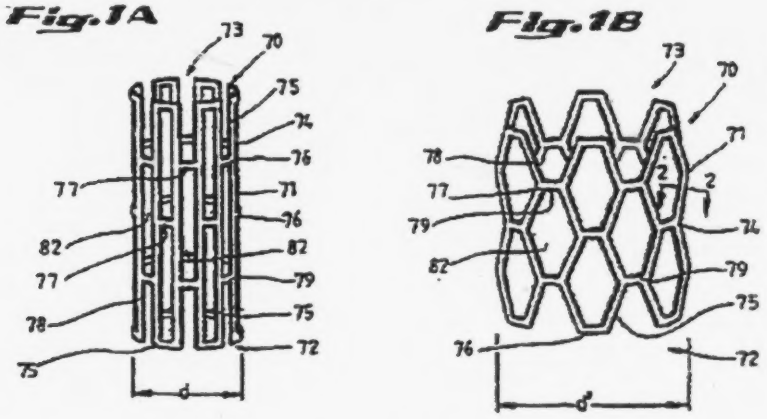
B. The Patents in Suit

1. The `762 Patent

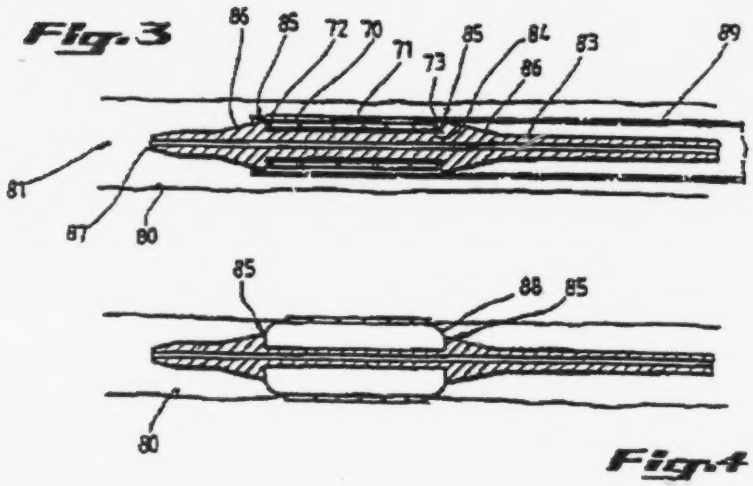
The `762 patent, entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft," is a continuation-in-part of patent application serial no. 796,009 (the "`009 application"), which issued as United States Patent No. 4,733,665 (the "`665 patent"). Dr. Julio C. Palmaz is the named inventor of the `762 patent, and plaintiff Expandable Grafts Partnership ("EGP") is the listed assignee. Dr.

Palmaz filed the `009 application on November 7, 1985, and the `762 patent issued on April 26, 1988. A reexamination certificate (the "`762 reexamination certificate") issued on October 27, 1998 with amended and additional claims.

The `762 patent includes both apparatus and method claims. The apparatus claims are directed to an expandable tubular member that serves as vascular scaffolding. Figures 1A and 1B shown below depict the preferred embodiment of the `762 patent in its unexpanded state ("first diameter") and expanded state ("second diameter"), respectively.



The method claims of the `762 patent describe the process of implanting the stent into a diseased vessel. As depicted in Figures 3 and 4 below, a stent is mounted upon a catheter and delivered in its first diameter to the diseased vessel. Next, the stent is expanded and deformed radially into contact with the vessel. Finally, the balloon is deflated and removed along with the catheter, leaving the stent in the artery to support the vessel wall.



Claim 23 of the `762 patent is an apparatus claim which is dependent upon claim 13.[2] The claims read:

> 13. An expandable intraluminal vascular graft, comprising:
>
> a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;
>
> the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and

[2] Claim 13 was cancelled during reexamination of the `762 patent. (`762 reexamination certificate, col. 1, ln. 34)

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

23. The expandable intraluminal vascular graft of claim 13, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.

('762 patent, col. 11, ln. 63 - col. 12, ln. 14; col. 12, lns. 56-59)

Claim 44, a method claim added during reexamination, reads:

44. A method for implanting a balloon expandable stent prosthesis within a passageway of a coronary artery having an area of stenosis, comprising the steps of:

utilizing a thin-walled, tubular member as the stent prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

disposing the stent prosthesis and catheter having an inflatable balloon portion;

inserting the stent prosthesis and catheter within the passageway by percutaneous catheterization;

delivering the catheter and stent prosthesis to the area of stenosis without surgically exposing the area of the passageway; and

expanding and deforming the stent prosthesis at the area of stenosis within the coronary artery passageway by expanding the inflatable balloon portion of the catheter associated with the stent prosthesis to force the stent prosthesis radially outwardly into contact with the area of stenosis in the passageway, the stent prosthesis being controllably deformed beyond its elastic limit.

(`762 reexamination certificate, col. 3, lns. 22-44)

Claims 51 and 54, also added during reexamination, read:

51. In combination, a balloon expandable stent prosthesis for implementation in the passageway of a coronary artery having an area of stenosis and a catheter comprising:

an expandable stent prosthesis being a thin-walled tubular member having first and second ends and a wall having an outer wall surface disposed between the first and second ends, the wall

surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

a catheter having an expandable, inflatable balloon portion;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member and the catheter into a lumen of a coronary artery having an area of stenosis and wherein the outside of the wall surface of the tubular member is a smooth surface when the tubular member has the first diameter; and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and controlled by the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the coronary artery in the area of stenosis.

54. The combination of claim 51, wherein said tubular member includes at least one ring portion defined by circumferentially adjacent slots so as to define a plurality of peak portions and valley portions.

(`762 reexamination certificate, col. 4, lns. 4-33, 41-44)

Prior to trial, the court construed disputed terms of the `762 patent as follows:

(1) "Graft" and "Prosthesis." A graft and prosthesis must be functional, that is, once it is expanded and deformed it must be capable of serving to prevent a body passageway from collapsing.

(2) "Tubular member." A discrete structure that has the form of a tube, that is, a hollow, elongated, usually cylindrical structure with two ends. "Elongate" is defined in the dictionary as "stretched out, lengthened; especially: having a form notably long in comparison to its width."

(3) "Thin-walled." The wall of the tubular member must have little extent from one surface to its opposite at both its first and second diameters.

(4) "Wall surface." The outer surface of the tubular member must be disposed in a common cylindrical plane.

(5) "Substantially uniform thickness." The thickness at all points along the wall surface of the tubular member, both at its first and second diameters, must be substantially the same. Variances as little as .001 inches fall outside the scope of "substantially uniform."

(6) "Plurality of slots." More than one slot. A "slot" is a long and narrow opening or groove, an opening whose

length is substantially greater than its width. The claim requires slots in the tubular members that run substantially parallel to the longitudinal axis.

(7) "Slots formed therein." Slots must be formed in the wall surface of a tubular member, as by the removal of material.

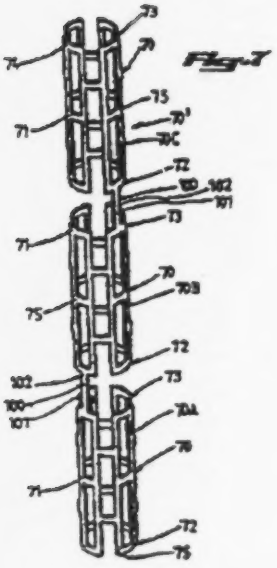
(8) "Smooth surface." The outside of the wall surface of the unexpanded tubular member has a continuously even surface, without roughness, points, bumps or ridges, especially to the touch.

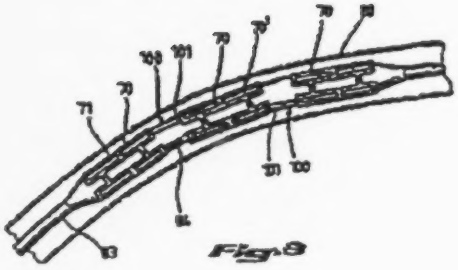
(D.I. 790, 1115, 1116)

2. The `984 Patent

The `984 patent, entitled "Expandable Intraluminal Graft," was filed on February 19, 1991 as a continuation of abandoned patent application serial number 253,115, filed on October 4, 1988. Dr. Richard A. Schatz is the named inventor, and EGP is the listed assignee. The `984 patent is directed to an improvement upon prior art stents, namely, connecting tubular members to "permit[] tissue of an elongated section of a body passageway to be supported by an elongated graft; and provide[] the necessary flexibility to negotiate the bends and curves in tortuous body passageways, such as the vascular system." (`984 patent, col. 4, lns. 20-25)

Figures 7 and 8 depict the angularly offset connector members of the `984 patent and the resulting added flexibility in a body passageway.





Claims 1 and 3 of the `984 patent read:

1. An expandable intraluminal vascular graft, comprising:

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

only one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members, the connector member being disposed in a substantially parallel relationship with respect to the longitudinal axis of the tubular

members and coplanar with each tubular member;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.

3. The expandable intraluminal graft of claim 1, wherein a first connector member is disposed between the second end of a first tubular member and the first end of a second tubular member; a second connector member is disposed between the second end of the second tubular member and the first end of a third tubular member, the first and second connector members being angularly offset from one another and with respect to the longitudinal axes of the tubular members they interconnect.

(`984 patent, col. 11, ln. 44 - col. 12, ln. 8; col. 12, lns. 13-22)

The court construed disputed terms of the `984 patent as follows:[3]

(1) "only one." A single unit and no more.

(2) "Connector member." A discrete structure disposed or particularly arranged between adjacent tubular members in order to join them together.

(3) "To flexibly connect adjacent tubular members." To connect in such a way as to allow turning, bowing or twisting without breaking. The connector member must provide flexibility, whether or not the adjacent tubular members themselves are flexible.

(4) "Substantially parallel." The connector member must run in substantially the same direction as the longitudinal axis of the adjacent tubular members. This means that the slots and the connectors run in the same direction and are substantially aligned with one another.

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[3] Terms appearing in both the `762 and `984 patents are construed consistently.

(5) "Coplanar." The connector member must lie within the planes formed by the inner and outer wall surfaces of the adjacent tubular members.

(D.I. 790, 1115)

3. The `332 Patent

The `332 patent, entitled "Expandable Intraluminal Graft," was filed on November 24, 1992 as a continuation of patent application no. 07/657,296, which issued as the `984 patent. The specification of the `332 patent, therefore, is virtually identical to that of the `984 patent.

Claim 22 of the `332 patent reads:

22. A balloon expandable coronary stent for delivery to a coronary artery through an access artery, the stent comprising:

at least two segments, each segment having a generally tubular shape and a first end and a second end;

each segment having a plurality of openings that are disposed substantially parallel to the longitudinal axis of the segment, the openings forming a series of alternating open and closed portions in each of the first and second ends of the segment;

the segments being arranged so that at least one closed portion of the second end of a first segment is in longitudinal alignment with a closed portion of the first end of a second segment;

a connector extending between and connecting the aligned closed portion of the second end of the first segment to the aligned closed portion of the first end of the second segment, the connector being an elongate flexible member that extends between and is integrally formed with the aligned closed portions;

whereby each of the segments may be displaced at an angle with respect to the longitudinal axis of an adjacent segment when the stent is delivered through a curved portion of the access or coronary arteries; and

the stent having a first diameter which permits intraluminal delivery of the stent through the access artery by percutaneous catheterization and a second, expanded and deformed diameter, the second diameter being attained upon the application from the interior of the stent of a radially, outwardly directed force by inflating a balloon, which second diameter is variable and dependent upon the amount of force applied to the stent, whereby the stent may be expanded and deformed beyond its elastic limit to expand the lumen of the coronary artery.

('332 patent, col. 13, ln. 13 - col. 14, ln. 13)

The court construed disputed terms of the `332 patent as follows:

(1) "Segment." A piece or separate fragment of something; one of the constituent parts into which a body is or may be divided.

(2) "Generally tubular shape." The phrase "segment having a generally tubular shape" is broader in scope than the phrase '"tubular member" and may encompass segments that are not perfectly hollow, elongated or cylindrical in shape.

(3) "Plurality of openings." More than one opening, that is, more than one breach or aperture.

(4) "Openings forming a series of alternating open and closed portions." All openings have "open" and "closed" portions, the closed portions comprising the material that gives form to or encloses the openings and serves to block or shut off entry or passage in some fashion. The claim requires that the openings in the segment alternate around the circumference so that each end of the segment consists of alternating open and closed portions. The court construes the phrase at issue to mean a combination of openings, some of which are "open," that is, without enclosing material at the end of the segment, thus permitting ingress and egress, and some of which are

"closed," that is, having enclosing material at the end of the segment thus blocking or shutting off entry or passage.

(5) "Connector." A discrete structure disposed or particularly arranged between adjacent tubular members in order to join them together. The language of the claim ("comprising . . . a connector") does not require that the claim be limited to a single connector.

(6) "Whereby each of the segments may be displaced at an angle with respect to the longitudinal axis of an adjacent segment when the stent is delivered through a curved portion of the access or coronary arteries." "Displaced" means to remove from the usual or proper place, to put out of place. An "angle" is a figure formed by two lines diverging from the same point or by two surfaces diverging from the same line. "Axis" is defined as a straight line with respect to which a body or figure, or system of points is either radially or bilaterally symmetrical. The phrase modifies the word "segment;" the phrase as written indicates that the entire segment (not a portion thereof) must be capable of angular displacement with respect to the longitudinal axis of the adjacent segment (not a portion thereof). In light of the specification, which

> speaks only in terms of a connector being disposed to flexibly connect rather than in terms of flexible segments, the court concludes that the limitation requires relatively rigid segments and relatively flexible connectors.

(D.I. 790, 1116)

4. The `312 and `370 Patents

The `312 patent, entitled "Stent Having a Multiplicity of Closed Circular Structures," was filed on February 25, 1994 by inventors Robert E. Fischell, David R. Fischell and Tim A. Fischell. The `370 patent, entitled "Stent Having a Multiplicity of Undulating Longitudinals," was filed on May 28, 1997 as a continuation of patent application serial no. 08/202,128, which issued as the `312 patent. Thus, the `312 and `370 patents have virtually identical specifications. The patents are directed to stents containing generally circular "rings" for radial strength upon expansion and "undulating longitudinals" for added flexibility. (`312 and `370 patents, col. 1, lns. 40-55)

Claim 21 of the `312 patent reads:

> 21. A predeployment stent structure adapted for placement in curved vessels of the coronary arteries, the stent structure being in the form of a thin-walled metal cylinder having a longitudinal axis, the stent including at least two undulating longitudinal structures each longitudinal structure having a multiplicity of straight sections and undulating sections with each straight section

> being joined continuously to at least one undulating section, the straight sections of all of the longitudinal structures being generally parallel to the longitudinal axis of the stent, the undulating sections of each longitudinal structure being of a generally curved shape so as to allow each undulating longitudinal structure to readily expand and contract in length when the stent is bent while passing through a curved coronary artery.

('312 patent, col. 7, lns. 4-17)

Claim 25 of the `370 patent is dependent upon claim 22. The claims read:

> 22. A pre-deployment balloon expandable stent structure adapted for percutaneous delivery to the curved coronary arteries, the stent structure being generally in the form of a thin-walled metal tube having a longitudinal axis, the stent structure having a multiplicity of closed perimeter cells, each cell having one or more undulating sections, each undulating section having a generally curved shape and having a first end point and a second end point wherein a line drawn from the first end point to the second end point is generally parallel to the stent's longitudinal axis.
>
> 25. The stent of claim 22 wherein the undulating section of each closed perimeter cell comprises a "U" shaped curve.

(`370 patent, col. 6, lns. 17-26, 35-36)

Claim 26 of the `370 patent reads:

> 26. A balloon expandable coronary stent comprising:
> (a) a stent in the form of a thin-walled metal tube capable of being mounted on an expandable balloon for percutaneous delivery of the stent into a coronary artery, the stent having a plurality of zig-zag segments, the zig-zag segments capable of being expanded by the balloon; and
> (b) a plurality of longitudinally undulating sections of a generally curved shape positioned between and connection the zig-zag segments, wherein the plurality of longitudinally undulating sections can expand and contract in length while being passed through a curved coronary artery.

(`370 patent, col. 6, lns. 37-49)

The court construed disputed terms of the `312 and `370 patents as follows:

> (1) "Undulating." Rising and falling in waves, thus having at least a crest and a trough.
>
> (2) "Longitudinals' and "longitudinal structures." Structures that extend or run lengthwise, in the direction of the stent's longitudinal axis. Although there is no requirement that the longitudinals or longitudinal structures extend the entire length of the stent, the structures have to extend long

enough to be considered continuous across a number of points of support.

(3) "Closed perimeter cells." A relatively small area on the perimeter of the stent that is bounded on all sides by continuous metal. The word "close" means to block or shut off entry or passage. The word "perimeter" means the boundary of a closed plane figure; outer limits.

(4) "Zig-zag segments." A portion of a stent that has one or more short sharp turns or angles.

(5) "Stent" or ""stent structure." A device used to support, expand or hold open an artery or other body passageway.

(D.I. 1116; *D.I. 154[4])

C. The Accused Devices

1. AVE' s MicroStent II, GFX and GFX2 Stents

The stents manufactured by AVE at issue in this case include the MicroStent II, GFX, and GFX2 stents (the "AVE stents").[5] The AVE stents consist of multiple sinusoidal

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[4] Docket item numbers designated with an asterisk refer to documents filed in Civil Action No. 98-197-SLR.

[5] Although Cordis alleged that AVE's MicroStent I also infringed the asserted patent claims, that question was not submitted to the jury because the court determined that Cordis had not presented

segments fused together to form a continuously connected device. Each sinusoidal segment is made from a torus, a circular-shaped object that has a circular cross-sectional shape, similar to a doughnut. AVE refers to these tori as "rings." After undergoing a heating process, the rings are bent from their normal configuration into a sinusoidal design characterized by a series of peaks and valleys called "crowns" interconnected by substantially straight portions called "struts." The segments are connected by fusing adjacent crowns together while the segments are positioned end to end in a helical arrangement. The crowns are fused to form a joint or weld using AVE's proprietary autogenous laser fusion process, which melts and fuses existing material from the two crowns so as to ultimately decrease the distance between them. Although it is still possible to identify the fused region using high magnification, there are no discrete sides, facets, faces, or other recognizable geometric features to the fused joints, which have a generally hourglass shape. There is only one weld between adjacent segments. The following is a drawing of an AVE stent with one of its welds circled:

The segments of the MicroStent II have four upper and lower crowns and are 3 mm in length. The segments of the GFX and GFX2 have six upper and lower crowns and are 2 mm in length. The AVE stents are constructed in a variety of sizes and lengths, created by connecting a number of individual 3 mm MicroStent II or 2 mm GFX segments

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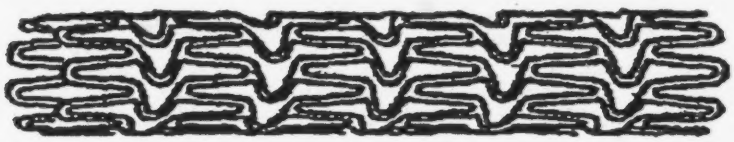
sufficient evidence on the issue during trial. (D.I. 965 at 2202-03; D.I. 966 at 2275-86)

together. They are no longer manufactured by AVE. (D.I. 296 at 3-9)

2. BSC's NIR Stent

The NIR stent is the only stent manufactured by BSC that is at issue in this litigation. It is manufactured from a flat sheet of metal upon which a design is etched. The sheet is then rolled into a cylindrical shape and the ends welded together, resulting in a stent composed of segments connected by U-shaped structures. (*D.I. 201 at 1924-27) A drawing of the NIR stent appears below.



D. The Trial

On November 6, 2000, the court commenced a seven-week jury trial in this case, with two separate juries (the "AVE jury" and the "BSC jury"), in four separate phases, per the parties' request.[6] In the first phase of the trial, the AVE jury determined whether the AVE stents infringed the asserted patent claims. In the second phase, the BSC jury determined whether BSC's NIR stent infringed the asserted patent claims. After reaching a verdict regarding BSC's liability, the BSC jury determined damages owed by BSC. Finally, the AVE jury returned after a three-week hiatus to determine damages owed by AVE.[7]

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[6] The court will refer to the portion of the trial against AVE as the "AVE trial" and the portion of the trial against BSC as the "BSC trial."

[7] The parties requested a "double bifurcation" of the trial to assist the lost profits damages analysis. To receive lost profits, a patentee must prove an absence of non-infringing alternatives. See Rite-Hite

On November 21, 2000, the AVE jury returned a verdict finding that the AVE stents infringed claims 23, 51 and 54 of the `762 patent and claims 1 and 3 of the `984 patent under the doctrine of equivalents.[8] (D.I. 955) The AVE jury also found that the above claims were not invalid for failure to comply with the written description requirement. (Id.) On December 22, 2000, the AVE jury awarded Cordis $271,075,085 in damages, including $192,800,460 in lost profits, $77,274,625 based on a 25% reasonable royalty for domestic sales of stents, and a $1,000,000 payment for foreign sales of stents made in the United States. (D.I. 1013)

On December 11, 2000, the BSC jury returned the following verdict regarding the liability of BSC over its NIR stent:

(1) Claim 23 of the `762 patent: no literal infringement; infringement under the doctrine of equivalents.

(2) Claim 44 of the `762 patent: contributory infringement; invalid pursuant to 35 U.S.C. § 305.

Corp. v. Kelley Co., 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc) (citing Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir. 1978)). Thus, Cordis' ability to present a claim for lost profits in either case was contingent upon first receiving verdicts of infringement in both cases.

[8] Neither the jury charge nor the verdict form in the AVE trial distinguished between literal infringement and infringement under the doctrine of equivalents because the court previously granted AVE's motion for summary judgment of no literal infringement. The jury was given a general instruction on "infringement" which mirrored a doctrine of equivalents instruction.

(3) Claim 22 of the `332 patent: no literal infringement; no infringement under the doctrine of equivalents; invalid for obviousness; not invalid for failure to comply with the written description requirement.

(4) Claim 21 of the `312 patent: no literal infringement;[9] not invalid for obviousness; not invalid for failure to comply with the written description requirement.

(5) Claim 25 of the `370 patent: literal infringement, but no infringement by the reverse doctrine of equivalents; not invalid for failure to comply with the written description requirement.

(6) Claim 26 of the `370 patent: literal infringement, but no infringement by the reverse doctrine of equivalents; invalid for failure to comply with the written description requirement.

(*D.I. 182) On December 15, 2000, the BSC jury awarded Cordis $324,403,250 in damages, including $253,595,750 in lost profits and $70,807,500 based on a 20% reasonable royalty rate. (*D.I. 189)

On February 7, 2001, the court commenced a four-day bench trial on the issue of unenforceability. The court's

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[9] Cordis did not assert infringement under the doctrine of equivalents on this claim.

findings of fact and conclusions of law are rendered in the instant opinion.

III. STANDARDS OF REVIEW

A. Motion for Judgment as a Matter of Law

To prevail on a renewed motion for judgment as a matter of law following a jury trial, the moving party "'must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusions implied (by) the jury's verdict cannot in law be supported by those findings.'" Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998) (quoting Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984)). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be acceptable by a reasonable mind as adequate to support the finding under review." Perkin-Elmer Corp., 732 F.2d at 893. In assessing the sufficiency of the evidence, the court must give the non-moving party, "as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor, and in general, view the record in the light most favorable to him." Williamson v. Consol. Rail Corp., 926 F.2d 1344, 1348 (3d Cir. 1991); Perkin-Elmer Corp., 732 F.2d at 893. The court may not determine the credibility of the witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." Perkin-Elmer Corp., 732 F.2d at 893. In sum, the court must determine whether the evidence reasonably supports the jury's verdict. See Dawn Equip. Co. v. Ky. Farms, Inc., 140 F.3d 1009, 1014 (Fed. Cir. 1998).

B. Motion for a New Trial

Federal Rule of Civil Procedure 59(a) provides, in pertinent part:

> A new trial may be granted to all or any of the parties and on all or part of the issues in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States.

Fed. R. Civ. P. 59(a). The decision to grant or deny a new trial is within the sound discretion of the trial court and, unlike the standard for determining judgment as a matter of law, the court need not view the evidence in the light most favorable to the verdict winner. See Allied Chem. Corp. v. Darflon, Inc., 449 U.S. 33, 36 (1980); Olefins Trading, Inc. v. Han Yang Chem. Corp., 9 F.3d 282 (3d Cir. 1993); LifeScan Inc. v. Home Diagnostics, Inc., 103 F. Supp.2d 345, 350 (D. Del. 2000), aff'd per curiam, Nos. 00-1485, 00-1486, 2001 WL 345439 (Fed. Cir. Apr. 6, 2001) (citations omitted). Among the most common reasons for granting a new trial are: (1) the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage of justice; (2) newly-discovered evidence exists that would likely alter the outcome of the trial; (3) improper conduct by an attorney or the court unfairly influenced the verdict; or (4) the jury's verdict was facially inconsistent. See Zarow-Smith v. N.J. Transit Rail Operations, 953 F. Supp. 581, 584 (D.N.J. 1997) (citations omitted). The court must proceed cautiously, mindful that it must not substitute its own judgment of the facts and the credibility of the witnesses for those of the jury. The court should grant a new trial on the basis that the verdict was against the weight of the evidence only where a miscarriage of justice would result if the verdict were to stand. See

Williamson, 926 F.2d at 1352; EEOC v. Del. Dep't of Health and Soc. Servs., 865 F.2d 1408, 1413 (3d Cir. 1989).

IV. CORDIS' STANDING TO SUE

In yet another challenge to Cordis' standing to sue, AVE and BSC argue that Ethicon NJ, a former exclusive licensee to the patents in suit, did not validly transfer its exclusive license to Technicare/Ethicon Ohio, a company with which it merged. This break in the chain of title, according to AVE and BSC, left Cordis with no right to sue on the patents. The court examined the corporate transactions that led to Cordis' license when it denied in part and granted in part ACS's motion to dismiss for lack of standing.[10] (D.I. 162) The court declines to repeat this exercise, and maintains that Cordis was assigned an exclusive license to the patents at the time the complaint was filed.

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[10] The court offered the following reasoning for its decision:

> The fact that the licensor may not have given its "express written consent" at the time of each corporate transformation is of no moment, where the parties' course of conduct over the years has been consistent with the licensor's knowledge and approval of the series of assignments.

(D.I. 162 at 4-5)

V. INFRINGEMENT, INVALIDITY AND DAMAGES[11]

A. Infringement and Invalidity - AVE Trial

1. Infringement of Claims 23, 51 and 54 of the `762 Patent

A determination of infringement requires a two-step analysis. First, the court must construe the asserted claims so as to ascertain their meaning and scope. Second, the claims as construed are compared to the accused product. See KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1355 (Fed. Cir. 2000). Claim construction is a question of law while infringement is a question of fact. See id. To establish literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly." Southwall Tech., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed. Cir. 1995). An accused product that does not literally infringe a claim may still infringe under the doctrine of equivalents if each limitation of the claim is met in the accused product either literally or equivalently. See Sextant Avionique, S.A. v Analog Devices, Inc., 172 F.3d 817, 826 (Fed. Cir. 1999). An element in an accused product is equivalent to a claim limitation if the differences between the two are "insubstantial" to one of ordinary skill in the art. KCJ Corp., 223 F.3d at 1359. A fact finder may also determine equivalence by assessing whether an element "does substantially the same thing in substantially the same way to get substantially the same result" as a claim

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[11] Throughout their briefs, the parties make numerous arguments challenging the court's construction of various terms in the asserted claims. The court went through the claim construction exercise on multiple occasions during the course of these protracted proceedings and declines to readdress its conclusions on claim construction in this opinion.

limitation. Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1260 (Fed. Cir. 1989).

Occasionally, "the issue of literal infringement may be resolved with the step of claim construction, for upon correct claim construction, it may be apparent whether the accused device is within the claims." Multiform Desiccants Inc. v. Medzam, 133 F.3d 1473, 1476 (Fed. Cir. 1998). Similarly, the determination of infringement under the doctrine of equivalents may be limited as a matter of law. For example, a finding of infringement under the doctrine of equivalents is barred if a claim was amended during prosecution to overcome the prior art. See Festo Corp., v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 585 (Fed. Cir. 2000) (en banc), cert. granted, 69 U.S.L.W. 3673 (U.S. June 18, 2001) (No. 00-1543). The scope of equivalents may also be limited by statements in the specification or prosecution history that disclaim coverage of certain subject matter. See Pharmacia & Upjohn Co. v. Mylan Pharms., Inc., 170 F.3d 1373, 1377 (Fed. Cir. 1999); Dawn Equip., 140 F.3d at 1016.

In the case at bar, the court granted AVE's motion for summary judgment of no literal infringement of claim 23 of the `762 patent by the AVE stents because they did not literally meet the "plurality of slots formed therein" limitation.[12] AVE now challenges the jury's finding that the AVE stents met that limitation by equivalence, arguing that the addition of the "formed therein" language to claim 13 of the `762 patent constitutes a narrowing amendment to the

[12] The `762 reexamination certificate, which added claims 51 and 54, issued after AVE filed its motion for summary judgment of no literal infringement of claim 23. Because the limitation "plurality of slots formed therein" is also present in claims 51 and 54, the court holds that its finding of no literal infringement of claim 23 by the AVE stents is also applicable to claims 51 and 54.

`009 application which bars Cordis from asserting the doctrine of equivalents on claim 23 under Festo.

In discussing the relationship between the doctrine of equivalents and prosecution history estoppel, the Federal Circuit in Festo ascribed to the doctrine of equivalents the purpose of "prevent[ing] an accused infringer from avoiding liability for infringement by changing only minor or insubstantial details of a claimed invention while retaining the invention's essential identity." Festo, 234 F.3d at 564. Prosecution history estoppel, on the other hand, is an equitable tool "that prevents the doctrine of equivalents from vitiating the notice function of claims." Id. More specifically, "'[p]rosecution history estoppel precludes a patentee from obtaining under the doctrine of equivalents coverage of subject matter that has been relinquished during the prosecution of its patent application.'" Id. (quoting Pharmacia & Upjohn Co., 170 F.3d at 1376-77). "The standard for determining whether particular subject matter was relinquished is an objective one that depends on what a competitor reasonably would conclude from the patent's prosecution history." Mark I Mktg. Corp. v. R.R. Donnelley & Sons Co., 66 F.3d 285, 291 (Fed. Cir. 1995). In this regard, "[t]he prosecution history must be examined as a whole."[13] Id.

Original claim 19 of the `009 application, the precursor to claim 13 of the `762 patent, is a relatively broad claim, covering both the woven wire mesh and slotted tube embodiments of the "expandable intraluminal graft" first

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[13] Because "[t]he application of prosecution history estoppel is a question of law," LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n, 867 F.2d 1572, 1576 (Fed. Cir. 1989), the issue was not presented to the jury but was preserved for post-trial review.

introduced by the `665 patent. The claim reads in relevant part:[14]

> [A] tubular shaped member having first and second ends and a wall surface disposed between the first and second ends, the wall surface being formed by a plurality of intersecting elongate members, at least some of the elongate members intersecting with one another intermediate the first and second ends of the tubular member . . .

(PX 10 at 2353-54) (emphasis added)

As explained in greater detail in the court's claim construction analysis, claim 13 of the `762 patent is narrower in scope, describing only one of the embodiments covered by the `665 patent, that is, the slotted tube embodiment. Claim 13 requires

> a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein . . .

(`762 patent, col. 11, lns. 64-68) (emphasis added) The court opined that, unlike the tubular member of the `665 patent whose wall surface is formed by "intersecting elongate members," the tubular member claimed by the `762 patent starts with a wall surface and the elongate members are

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[14] Claims 13 and 18 of the `665 patent as it issued in March 1988 mirror this same languague.

formed by removing material from the wall surface (to wit, "slots [are] formed therein"). (D.I. 464 at 10-17)

In light of this background, it is the court's conclusion that Cordis is not entitled to the protection of the doctrine of equivalents with respect to tubular members that do not have a pre-existing wall surface, such as the AVE stents. The patentee at bar chose to more narrowly define his invention in the `762 patent by emphasizing a specific feature of the balloon expandable intraluminal graft - a pre-existing wall surface that was required to have certain characteristics, i.e., "thin-walled," the wall surface having a "substantially uniform thickness," and "a plurality of slots formed therein." The notice function of patent claims would be ill served if this court were to allow Cordis, under the guise of equivalency, to embrace within the scope of the `762 patent stents lacking the very feature that distinguishes the `762 patent from the broader `665 patent. A competitor reviewing the development of Dr. Palmaz's slotted tube invention reasonably would conclude that a tubular member whose wall surface is formed by bending wire does not fall within the scope of claim 23 of the `762 patent. Therefore, the range of equivalents sought by Cordis is barred by the prosecution history of the `762 patent and the jury's verdict of infringement under the doctrine of equivalents is reversed.

2. Invalidity of Claims 23, 51 and 54 of the '762 Patent

AVE challenges the jury's verdict that the asserted claims of the `762 patent are not invalid for failure to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1, which provides:

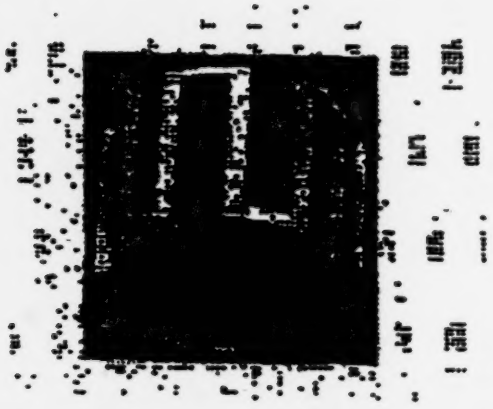
> The specification shall contain a written description of the invention, and of the

> manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1.

Patent claims are presumed valid. See 35 U.S.C. § 282. See also Intervet Am., Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1054 (Fed. Cir. 1989) ("The presumption of validity under 35 U.S.C. § 282 carries with it a presumption the examiner did his duty and knew what claims he was allowing."). To overcome this presumption, AVE was required to "provide clear and convincing evidence that persons skilled in the art would not recognize in the disclosure a description of the claimed invention." Biacore v. Thermo Bioanalysis Corp., 79 F. Supp.2d 422, 467 (D. Del. 1999), aff'd per curiam, Nos. 01-1337, 01-1446, 2002 WL 418166 (Fed. Cir. Mar. 15, 2002).

AVE contends that Cordis' use of the "building block" theory during trial renders claims 23, 51 and 54 of the asserted claims of the `762 patent invalid for failure to comply with the written description requirement. The "building block," shown below, is essentially a severed portion of Figure 1A of the `762 patent, resembling a completely half-slotted stent.



AVE argues that the specification of the `762 patent fails to contemplate an all half-slotted stent and, therefore, the court should either find the asserted claims invalid as a matter of law, or clarify the definition of "plurality of slots" to require at least one complete slot.

The court has declined over the course of these proceedings to limit the word "slot" to a long and narrow opening that is completely surrounded by material (i.e., a closed or complete slot), based on the ordinary meaning of the word (e.g., the "slots" of a comb) and the fact that each of Dr. Palmaz's tubular structures had to have open or half-slots in order to expand. The tension between adequate disclosure of the scope of an invention and construing claims more broadly than the preferred embodiment has permeated the litigation at bar. The court declines to revisit the question. AVE's motion for judgment as a matter of law on this issue is denied.[15]

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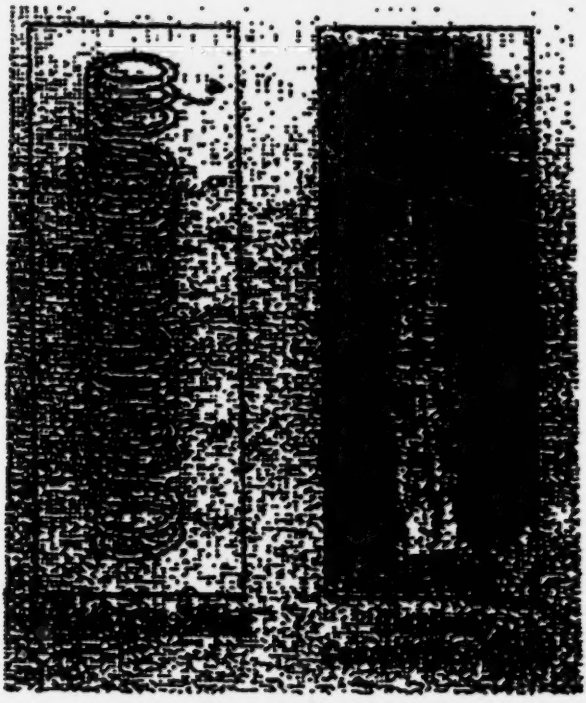
[15] To the extent that AVE argues that claims 1 and 3 of the `984 patent are invalid for failing to satisfy the written description requirement, the court maintains that this defense was never a part of the case, and AVE is barred from raising it at this time. (D.I. 963 at 1365)

3. Infringement of Claims 1 and 3 of the `984 Patent

Prior to trial, the court granted AVE's motion for no literal infringement of claims 1 and 3 of the `984 patent because the AVE stents did not literally contain the "plurality of slots formed therein" limitation. (D.I. 462) AVE now challenges the jury's finding that its stents infringed claims 1 and 3 under the doctrine of equivalents because of arguments made by the patentee during prosecution of the `984 patent to distinguish two prior art references: United States Patent No. 4,969,458 ("Wiktor") and the Gianturco Connected Z-Stent disclosed in an article by Tetsuya Yoshioka, et al., entitled, "Self-Expanding Endovascular Graft: An Experimental Study in Dogs," published in the American Journal of Roentgenology in October 1988 ("Yoshioka"). (AVEX 438) The "bent wire" stents disclosed by Wiktor and Yoshioka are reproduced below.



In arguing that "Wiktor is simply not responsive to the claimed structural limitations of [c]laims 1 and 4," the patentee explained that

> Wiktor does not disclose a plurality of "thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member." Wiktor discloses a single stent, or graft made up of coiled wire. There is no wall surface having a plurality of slots,

> nor slots disposed parallel to the longitudinal axis of each tubular member.

(PX 16, Tab 49 at 631) (emphasis added) A reasonable interpretation of this declaration is that the patentee surrendered bent wire stents, as AVE argues.

Such an interpretation is consistent with the prosecution history of the `984 patent, which is replete with references to the `665 and `762 patents, describing such prior art as disclosing

> expandable intraluminal grafts and methods and apparatus for implanting expandable intraluminal grafts which may be used in practicing the present invention. These three patents are commonly owned with the present application.

(PX 16, Tab 19 at 509; see also Id., Tab 22 at 518) The above statement reflects the fact that the `665, `762 and `984 patents, among others, share essentially the same specification and the `984 patent claims the same basic structure (albeit in multiples) in the same language as does the `762 patent, to wit:

> [A] plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member.

(`984 patent, claims 1 and 4, col. 11, lns. 46-52; col. 12, lns 25-31) (emphasis added) Given the common history of the `762 and `984 patents, this court construed common claim limitations consistently. Having found that the patentee of the `762 patent surrendered structures that have no pre-existing wall surface, it would be inequitable to find otherwise in connection with the `984 patent.

Therefore, Cordis is barred from asserting infringement of claims 1 and 3 of the `984 patent under the doctrine of equivalents. This conclusion is based upon the patentee's concession that Wiktor, a bent wire stent, does not disclose a "wall surface having a plurality of slots," as well as the common history of the `762 and `984 patents.

B. Infringement and Invalidity - BSC Trial

1. Infringement of Claim 23 of the `762 Patent

The jury determined that BSC's NIR stent infringes claim 23 of the `762 patent under the doctrine of equivalents. BSC contends that prosecution history estoppel narrows or bars the application of the doctrine of equivalents to the "substantially uniform thickness," "wall surface"' and "smooth surface" limitations of claim 23, and that there was insufficient evidence to find that the NIR stent literally met any of those limitations. Because the jury was not given a detailed verdict form, the court must uphold the verdict only if it there was sufficient evidence to support a finding that the NIR stent meets one or more limitations by equivalence, and every other limitation literally. See, e.g., Comark, 156 F.3d at 1188. The court concludes that, although prosecution history estoppel bars the application of the doctrine of equivalents to the "substantially uniform thickness" limitation, Cordis presented substantial evidence to support a finding that the NIR stent contains that limitation literally,

and contains the "wall surface" and "smooth surface" limitations under the doctrine of equivalents. Thus, BSC's motion for judgment as a matter of law that claim 23 of the `762 patent is not infringed by the NIR stent is denied.[16]

a. "Substantially Uniform Thickness"

BSC contends that the patentee's efforts to distinguish United States Patent No. 3,657,744 ("Ersek") during reexamination of the `762 patent estops Cordis from asserting the doctrine of equivalents on the "substantially uniform thickness" limitation of claim 23. Ersek discloses a tubular structure that is manufactured by cutting openings in a flat sheet of metal, pulling the sheet to expand the openings, and then rolling the sheet into a cylindrical shape and welding it together. Expanding the openings causes the struts of the resulting metal tube to be twisted, enabling the structure to become embedded in tissue upon surgical implantation. (BSCX 6228, col. 2, ln. 56 - col. 3, ln. 9) Figures 2 and 5 of Ersek are shown below.

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[16] BSC also makes several arguments that Cordis is barred from asserting infringement of claim 23 under the doctrine of equivalents based on Festo and Intermatic, Inc. v. Lamson & Sessions Co., 273 F.3d 1355 (Fed. Cir. 2001). First, BSC argues that the addition of the terms "smooth surface" and "substantially uniform thickness" to claims 35 and 37 during reexamination bars the application of the doctrine of equivalents to claim 23, which also contains those limitations. Second, BSC claims that Cordis is estopped from asserting equivalence on the "smooth surface" limitation because of the cancellation of claim 13, from which claim 23 depends. Finally, BSC contends that Festo applies to argument-based estoppel as well as amendment-based estoppel. Because this court concludes that Cordis presented substantial evidence to support a finding that the NIR stent literally contains these limitations, and in light of the present review of Festo by the United States Supreme Court, this court declines to further address BSC's arguments.

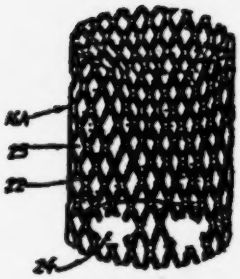

FIG. 2

FIG. 5

During reexamination, the patentee stated the following to distinguish Ersek from the claims of the '762 patent:

> As shown therein and in Ersek Figure 5, in the first diameter configuration, the wall of sleeve 16 is of varying thickness because the strands of the sleeve have twisted out of the plane of the starting material. Moreover, the bonds or bridges at the junctions of the strands protrude inwardly and outwardly of the plane of the starting material, and as a result the Ersek sleeve 16 has a non-uniform wall of varying thickness.

(PX 13 at 3049) The patentee also cited the "Antonsson Affidavit," which stated that Ersek's wall thickness "ranged from a minimum thickness of 0.0035 inches to a maximum thickness of 0.0045 inches." (PX 13 at 3050-51) The court integrated the patentee's arguments into its construction of the "substantially uniform thickness" limitation:

> The thickness at all points along the wall surface of the tubular member, both at its first and second diameters, must be substantially

> the same. Variances as little as .001 inches fall outside the scope of "substantially uniform."

(D.I. 790, 1116) (emphasis added)

BSC contends that Cordis is estopped from claiming equivalence of any accused device that has a variance in wall thickness of 0.001 inches or more. Having incorporated the patentee's arguments distinguishing Ersek into its claim construction, the court is now confronted with the often puzzling task of determining where claim construction ends and prosecution history estoppel begins. Under the reasoning employed in Moore U.S.A., Inc. v. Standard Register Co., 229 F.3d 1091, 1106 (Fed. Cir. 2000), cert. denied, 532 U.S. 1008 (2001), however, the court concludes that the term "substantially uniform" is not entitled to a scope of equivalents. First, consistent with the court's construction that a wall surface with a "substantially uniform thickness" must not vary more that .001 inches, to characterize as equivalent what is by definition not of a "substantially uniform thickness" would be to vitiate the limitation. Second, "it would defy logic to conclude that" a wall surface without a substantially uniform thickness "could be insubstantially different from a claim limitation requiring" a substantially uniform thickness, "and no reasonable juror could find otherwise." Id. Thus, as a matter of law, Cordis is estopped from claiming equivalence of any accused product whose wall surface varies in thickness by 0.001 inches or more.[17]

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[17] Cordis' contention that Ersek does not have a "substantially uniform thickness" because its tubular structure has areas that are several times the thickness of the starting material is misplaced. That argument was used to distinguish Ersek from the "thin-walled" limitation contained in certain claims of the '762 patent. (PX 13 at 3054-55)

Nevertheless, the court finds that Cordis presented substantial evidence at trial to support a finding that the NIR stent literally contains the "substantially uniform thickness" limitation. Drs. Buller and Collins relied on engineering drawings of the NIR stent to show that the thickness of its struts varies by only .0004 inches, which is within the court's definition. (*D.I. 197 at 757-58; *D.I. 198 at 1202; PX 3776) They also relied on a weld grind elimination report to show that about 25% of the welds on the NIR stent do not vary in thickness by more than 0.001 inches. (*D.I. 197 at 758-61, 932-33, 938-40; *D.I. 198 at 1198-99, 1202-04; PX 3745) Because the jury was entitled to accept Cordis' theory of individual tubular members serving as a basis for the infringement analysis, and each tubular member of the NIR stent contains one weld (*D.I. 198 at 1194), the jury reasonably concluded that the NIR stent literally contains the "substantially uniform thickness" limitation of claim 23.

b. "Smooth Surface"

BSC also argues that the patentee's efforts to distinguish Ersek during reexamination of the `762 patent estop Cordis from asserting the doctrine of equivalents on the "smooth surface" limitation. During reexamination, the patentee stated:

> A clear purpose of Dr. Palmaz's invention is to provide a low-profile, small diameter product that is smooth enough that it can be intraluminally delivered from a remote location to a desired location without the risk of damaging the body passageway.

(PX 13 at 3053) (emphasis added) Based on this argument, Cordis advocated a functional definition of "smooth surface" - that the surface be smooth enough for intraluminal delivery. The court determined, however, that the patent

claims suggested a narrower structural definition. Claim 13 requires a "tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen," whereas claim 23 requires that the "outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter." Thus, the inclusion of "smooth surface" in dependent claim 23 suggests that the term must mean more than simply "suitable for intraluminal delivery." The court adopted a dictionary definition of "smooth," also mentioned by the patentee in distinguishing Ersek from the '762 patent:

> The outside of the wall surface of the unexpanded tubular member has a continuously even surface, without roughness, points, bumps or ridges, especially to the touch.

(D.I. 790, 1116; PX 13 at 003049-50) Because the court incorporated the patentee's arguments distinguishing Ersek into a structural definition of "smooth surface" and finds no reason in the prosecution history to preclude a finding of equivalence, prosecution history estoppel does not narrow the doctrine of equivalents on this limitation.

Furthermore, the court finds that there was substantial evidence presented at trial to support a verdict that the NIR stent contains the "smooth surface" limitation either literally or under the doctrine of equivalents. Dr. Buller testified that the NIR stent has a "smooth surface," and an article by Dr. Kobi Richter in the Handbook of Coronary Stents, describes the NIR stent as having a "smooth surface." (*D.I. 197 at 766-68; *D.I. 200 at 1669; PX 275 at 134) Furthermore, the jury was given the opportunity to handle the NIR stent and determine if it was

"without roughness, points, bumps or ridges, especially to the touch." (*D.I. 199 at 1533) In sum, Cordis presented substantial evidence to support the jury's verdict and BSC's motion for judgment as a matter of law on this issue is denied.

c. "Wall Surface"

Finally, BSC contends that Cordis is estopped from asserting the doctrine of equivalents on the "wall surface" limitation of claim 23. The patentee distinguished Ersek as not having a "wall surface disposed between the first and second ends" because the wall of the stent was not "disposed in a common cylindrical plane:"

> As is evident from the specification of the `762 patent, with particular reference to Figure 1A, the connecting members and elongate members that collectively form the tubular member 71 have an outer surface that is disposed in a common cylindrical plane. No comparable wall surface is present in Ersek's fixation sleeve, and it would render Ersek inoperable for its intended purpose to modify sleeve 16 and eliminate the outwardly projecting edges, since the thus modified sleeve would eliminate the very structure contemplated by Ersek for retaining the associated graft or heart valve within the body passageway.

(PX 13 at 3054) Again, the court incorporated the patentee's prosecution arguments into its claim construction when it defined "wall surface" to require that the "outer surface of the tubular member must be disposed in a common cylindrical plane." The court finds no evidence in the prosecution history to preclude a finding of equivalence

based on this definition, thus, Cordis is not estopped from asserting the doctrine of equivalents on this limitation.

The court also finds that substantial evidence supports a finding that the NIR stent contains a "wall surface," either literally or under the doctrine of equivalents. Dr. Buller stated that the "tubular members of the NIR stent are disposed in a cylindrical shape . . . [i]t fulfills exactly that claim language," and that the welds lie in the same plane as the tubular members. (*D.I. 197 at 754-55) Dr. Collins also testified that the NIR stent's wall surface, including the welds, lies in a common cylindrical plane. (*D.I. 198 at 1201) In sum, the court finds that there is sufficient evidence in the record to support the jury's verdict.[18]

2. Contributory Infringement of Claim 44 of the `762 Patent

BSC argues that it is entitled to judgment as a matter of law that claim 44 of the `762 patent is not infringed or, in the alternative, to a new trial, for three reasons: (1) there is no predicate act of direct infringement by any one entity or related entities; (2) the NIR stent is suitable for substantial noninfringing use; and (3) Cordis failed to prove that BSC had the requisite knowledge for contributory infringement.

Pursuant to 35 U.S.C. § 271(c),

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[18] BSC's motion for a new trial to consider the reverse doctrine of equivalents for claims determined to be infringed under the doctrine of equivalents is denied. See Martin v. Barber, 755 F.2d 1564, 1567 n.1 (Fed. Cir. 1985) ("[The reverse doctrine of equivalents] becomes an issue only when the accused device falls within the literal words of a claim."). BSC's motion for a new trial to determine if the NIR stent infringes claim 23 under the doctrine of equivalents because the jury's verdict was against the weight of the evidence is also denied.

> [w]hoever offers to sell or sells within the United states or imports into the United States a component of a patented machine, manufacture, combination or composition, or part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

There can be no contributory infringement in the absence of direct infringement. See Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 341-42 (1961). Furthermore, "only proof of a defendant's knowledge, not intent, that his activity cause[s] infringement [is] necessary to establish contributory infringement." Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990).

a. Predicate Act of Direct Infringement

To constitute a predicate act of direct infringement of a process claim, either a single entity must perform every step of the method or, if two or more entities perform different steps of the method, those entities must have some connection to each other. See, e.g., Faroudja Labs., Inc. v. Dwin Elecs., Inc., No. 97-20010, 1999 WL 111788, at *5 (N.D. Cal. Feb. 24, 1999) ("It is true that several district courts have found a party liable for direct infringement of a process patent even where the various steps included in the patent are performed by distinct entities. However, these

cases indicate that some connection between the different entities justified that finding.").[19]

BSC argues that, although physicians who implant NIR stents in coronary arteries may carry out some of the first, third, fourth and fifth steps of the method of claim 44 - utilizing, inserting, delivering and expanding the NIR stent, respectively - they do not carry out the second step of "disposing" the NIR stent on a balloon catheter. Rather, BSC performs this step by selling the NIR stent in the United States premounted on a catheter, and BSC has no relationship to physicians who perform the other steps.

The court finds that there was sufficient evidence presented at trial to support the finding of the jury that BSC has "some connection" to physicians who implant the NIR stent. For instance, Dr. Buller testified about the relationship between BSC and the medical community:

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[19] During the jury charge conference, BSC argued that a higher standard is required to establish contributory infringement by related entities, one in which the entities must "work in concert," "work together jointly" or have an "agency" relationship. The court rejected these arguments and instead adopted the "some connection" standard used in the Faroudja case:

> Cordis must prove by a preponderance of the evidence each of the following to establish contributory infringement of claim 44, which covers a method of medical treatment: . . .
>
> 5. That every step of the method of medical treatment described in claim 44 is performed either by a single entity, or by different persons or entities who have some connection to each other.

(D.I. 1116) (emphasis added) BSC now presents no arguments that compel the court to change its prior decision.

> There's a very close relationship. I think you heard evidence of the close relationship between Boston Scientific and its personnel and the doctors, and we, in all countries, in Europe as well, depend very much on industry for this relationship, for teaching us about new products, how to use them, when they're appropriate to be used and generally how the products perform and how they might benefit our patients.

(*D.I. 203 at 2549) He also testified that BSC supplies samples of the NIR stent to physicians, and recruits physicians to participate in clinical trials. (Id.)

BSC's chairman, Peter Nicholas, also testified about BSC's close relationship with physicians:

> Well, we have a network of thousands of people in the field. These are professional salespeople in the field all throughout the world. And they're talking to physicians every day. I think we talked to perhaps five, ten thousand physicians every single day with our organization. And we selected a handful, maybe 15 to 20 of those physicians throughout the world who are, in our view, really leaders, in the world. And we asked them to tell us about the NIR stent.

(*D.I. 199 at 1457) Thus, BSC's motion for judgment as a matter of law or a new trial on this issue is denied.

b. NIR Stent as a Staple Article of Commerce Suitable for

Substantial Noninfringing Use

BSC also challenges the jury's finding that the NIR stent is incapable of "substantial noninfringing uses." The court instructed the jury on this issue as follows:

> In determining whether the NIR stent is a "staple article of commerce," you should focus on the NIR stent actually supplied by Boston Scientific, and you should take into account the quality, quantity and efficiency of the suggested uses. That a product is known to have potential infringing uses is not sufficient to establish contributory infringement. You should also consider in this regard the uses for which the NIR stent has been approved by the FDA and the labeling and instructions of the NIR stent.

(D.I. 1116)

Although BSC presented evidence that the NIR stent is suitable for implantation in body passageways other than the coronary artery,[20] the court finds that the jury reasonably concluded that these uses are not "substantial." See Hoffmann-LaRoche, Inc., v. Promega Corp., No. C-93-1748-VRW, 1994 U.S. Dist. LEXIS 10174, at *29 (N.D. Cal. June 13, 1994) ("Whether a use is 'substantial' or not depends on

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[20] The instructions that accompany the NIR stent state that it may be used to treat lesions in saphenous vein grafts, and the NIR stent has been approved by the FDA for use in the biliary system. (PX 3796A; BSCX 9872; *D.I. 199 at 1464) Also, BSC's expert Dr. David Cumberland testified that the NIR stent is suitable for use in the renal arteries. (*D.I. 200 at 1602)

how likely and often the use will occur. Thus, occasional aberrant use of a product does not make that use 'substantial.' Similarly, inefficient and uneconomical uses are less likely to be deemed 'substantial.'") (citations omitted). BSC promotes the NIR stent to physicians as a coronary stent, and FDA-approved labeling states that the NIR stent is used only for "improving coronary lumen diameter." (PX 276 at 281; PX 3796A) Dr. Buller, a member of BSC's advisory board when the NIR stent was launched, testified that he was not aware of any "substantial" use of the NIR stent outside the coronary arteries. (*D.I. 197 at 781) In sum, the court finds that, based on the evidence presented, the jury reasonably determined that any uses of the NIR stent outside the coronary arteries are not "substantial."

c. BSC's Knowledge

Finally, BSC argues that Cordis failed to show that BSC possesses the requisite knowledge for contributory infringement:

> That BSC sold or supplied the NIR stent with knowledge that the NIR stent was especially made for use in the manner claimed in claim 44 of the `762 patent.

(D.I. 1116) See Hewlett-Packard, 909 F.2d at 1469 n.4 (citing Aro Mfg., 377 U.S. at 488). The court finds that Cordis presented substantial evidence to support the jury's finding that BSC possessed knowledge that the NIR stent is "especially adapted for a particular use proscribed by a known patent." Snuba Int'l v. Dolphin World, Inc., No. 99-1357, 2000 WL 961363, at *7 (Fed. Cir. July 11, 2000). BSC is aware of how the NIR stent is used and instructs physicians in that use. (PX 3796A) BSC's motion for judgment as a matter of law that its lacks the requisite

knowledge to establish contributory infringement of claim 44 is denied.

3. Invalidity of Claim 44 of the `762 Patent

Cordis moves for judgment as a matter of law that claim 44 of the `762 patent is not invalid for failure to comply with 35 U.S.C. § 305. Section 305 provides, in pertinent part:

> In any reexamination proceeding under this chapter, the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301 of this title,[21] or in response to a decision adverse to the patentability of a claim of a patent. No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding under this chapter.

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[21] Section 301 provides:

Any person at any time may cite to the Office in writing prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent. If the person explains in writing the pertinency and manner of applying such prior art to at least one claim of the patent, the citation of such prior art and the explanation thereof will become a part of the official file of the patent. At the written request of the person citing the prior art, his or her identity will be excluded from the patent file and kept confidential. 35 U.S.C. § 301.

35 U.S.C. § 305. Cordis argues that: (1) the question of invalidity under § 305 is one for the court and not the jury; and (2) claim 44 was added during reexamination for a proper purpose.

a. Question for the Court or the Jury

The Federal Circuit has characterized invalidity under § 305 as a question of law which it must review de novo. See In re Freeman, 30 F.3d 1459, 1464 (Fed. Cir. 1994) ("Whether amendments enlarge the scope of a claim is a matter of claim construction. Claim construction is a question of law which we review de novo.") (citing In re Donaldson Co., Inc., 16 F.3d 1189, 1192 (Fed. Cir. 1994)). During the trial, the court reserved decision on whether this issue is one for the court or jury, and allowed the jury to address the issue in the event that the court later determined that it was a jury question. (*D.I. 203 at 2493) Upon careful consideration, the court concludes that, pursuant to the language of the Federal Circuit in In re Freeman, invalidity under § 305 is a question for the court and not the jury. Although BSC argues that the specific issue at bar is not "whether amendments enlarge the scope of a claim," but rather, whether a claim was added for a proper purpose, the court finds no persuasive authority requiring a jury to decide such an issue, nor is such an issue an inappropriate question for the court. Contrary to BSC's position, the court may, and is often required to, address issues with similar factual underpinnings, such as prosecution history estoppel. Thus, the court shall decide the issue of invalidity of claim 44 under § 305, using the jury's verdict as an advisory opinion.

b. Reasons for Addition of Claim 44 in Reexamination

According to § 305, a claim may be added or amended upon reexamination for only two reasons: (1) to distinguish the invention as claimed from the prior art; or (2) in response to a decision adverse to the patentability of a claim of a patent. See 35 U.S.C. § 305. See also In re Freeman, 30 F.3d at 1468 ("[T]he ability of a patentee to amend claims during reexamination must be seen in light of the fundamental purpose of reexamination - the determination of validity in light of a substantial new question of patentability. Thus, amendment of claims during reexamination is limited to amendment in light of prior art raising a substantial new question of patentability.") (citing In re Yamamoto, 740 F.2d 1569, 1572 (Fed. Cir. 1984)). Cordis argues that claim 44 was added to the `762 patent for both permissible reasons, whereas BSC contends that claim 44 was added solely to cover the stents of Cordis' competitors.

In October 1997, reexamination of the `762 patent was requested in view of three additional pieces of prior art: Ersek, U.S.S.R. Inventor's Certificate 660689 ("Kononov"), and United States Patent No. 4,787,899 ("Lazarus"). (PX 12 at 1407) In a subsequent office action, the examiner rejected claims 1-8 and 35-38 as unpatentable under 35 U.S.C. § 103(a) in light of the additional prior art. (PX 13, Tab 32) The patentee then submitted an Amendment on July 21, 1998 that included an amended claim 1 and several additional claims, including claim 44. In its remarks accompanying the Amendment, the patentee stated:

> Claims 1, 13, 24, 35 and 37 have been amended in accordance with the discussions with Examiner Thaler at the above-noted

> interviews, and in subsequent telephone discussions on July 13, 1998. Added claims 44-59 are all narrower in scope than the original claims, and provide specific protection for aspects of the disclosed invention which have been incorporated into competitive products and methods.

(PX 13 at 3045-46) (emphasis added)

The only other mention of claim 44 in the prosecution history appears in the Examiner's Reasons for Allowance dated August 25, 1998. Examiner Thaler remarked:

> Claim 44 is a new claim. This claim includes the step of expanding and deforming the stent prosthesis at an area of stenosis within the coronary artery. This claim is more limited than amended claim 1. It would not have been obvious to locate either the Lazarus or the Kononov device within the coronary artery at the area of stenosis for substantially the same reasons as those [applicable to claim 1].

(PX 14 at 3256-57)

The court finds that claim 44 was added solely to cover competitors' stents, and not for a permissible reason under § 305. The patentee clearly stated that claim 44 was added to provide protection for "aspects of the disclosed invention which have been incorporated into competitive products and methods." Examiner Thaler's remarks about claim 44 pertain to the patentability of claim 44 itself, not how claim 44 enhances the patentability of claim 1. In fact,

Examiner Thaler's prior objections to claim 1 were withdrawn not because of claim 44, but because of the insertion of the phrase, "at the location of an existing natural obstruction within the body passageway," into claim 1. (PX 14 at 3254-56) Claim 44 is simply a narrower version of claim 1, and there is no indication in the prosecution history that claim 44 was added to distinguish the invention as claimed from the prior art, or in response to the original rejection of claim 1 for obviousness. Although a patentee may add claims to cover a competitor's product, the addition of those claims must comply with the patent laws. See Kingsdown Med. Consultants Ltd. v. Hollister, Inc., 863 F.2d 867, 874 (Fed. Cir. 1988). Because the court finds that claim 44 was not added for a permissible reason under § 305, Cordis' motion for judgment as a matter of law on this issue is denied.

4. Invalidity of Claim 22 of the '332 Patent

BSC contends that it is entitled to judgment as a matter of law that claim 22 of the `332 patent is invalid for failure to comply with the written description requirement because the specification of the `332 patent fails to disclose multiple connectors. The court finds that the jury reasonably concluded that BSC failed to demonstrate by clear and convincing evidence that claim 22 is invalid. The specification of the `332 patent states that "[t]he present invention includes . . . a single connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members," but never limits the invention to containing only single connector members. (`332 patent, col. 3, lns. 38-45) Moreover, because the `332 patent is a continuation of the `984 patent, the jury properly considered the specification and file history of the `984 patent, whose original claims were directed to a stent

"comprising . . . a single connector member being disposed between adjacent tubular members." (PX 16 at 431-42) The use of the open-ended term "comprising" suggests that multiple connectors may also be present. Furthermore, the prosecution history of the `984 patent contains several references to multiple connectors. (PX 16 at 575-76; PX 17 at 2885) The jury's verdict is consistent with the weight of the evidence, thus, BSC's motion for judgment as a matter of law on this issue is denied.

5. Infringement of Claims 25 and 26 of the `370 Patent

BSC challenges the jury's finding that the NIR stent literally infringes claims 25 and 26 of the `370 patent. Specifically, BSC contends that Cordis inappropriately altered the parties' and the court's understanding of the term "undulating" and, under the intended construction of the term, the evidence presented at trial does not support a conclusion that the NIR stent contains "undulating" sections.

During claim construction, the parties and the court agreed that the words "crest" and "trough" define arcing curves, not just points at the top or bottom of a curve.[22] With this understanding of the terms, the court defined "undulating" to mean "rising and falling in waves, thus having at least a crest and a trough." The use of the plural "waves" implies a change in direction, as suggested by Figure 8 of the `370 patent, shown below.

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[22] The court added the "crest" and "trough" language to address a dispute between the parties about whether "undulating" required both a crest and a trough, as opposed to a crest or a trough.

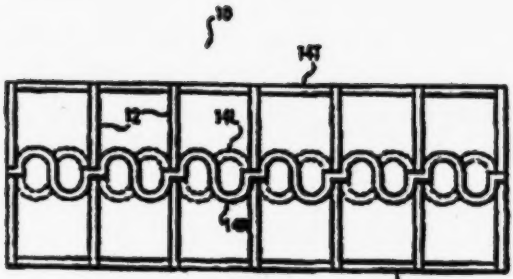

FIG.8

The court did not include the "change in direction" language in the claim construction because neither party suggested it was necessary, as it was contemplated under BSC's definition which was embraced by the court.

At trial, Cordis presented no evidence to suggest that the NIR stent has two arcing curves or waves which can be identified as a crest and a trough. Instead, Cordis argued that the "U" shaped member of the NIR stent represents one full cycle of a sine wave, which includes one crest (the combined two top points of the "U") and one trough (the "U" curve itself). (*D.I. 203 at 2631-33) Cordis' attempt at satisfying the court's claim construction, albeit creative, is unsuccessful. "To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly." Southwall Techs., 54 F.3d at 1574. The court finds that Cordis failed to present sufficient evidence to prove that the NIR stent literally contains "undulating" sections as defined by the court. BSC's motion for judgment as a matter of law on this issue is granted. Because the court finds that the NIR stent does not literally infringe claims 25 and 26 of the `370 patent, Cordis' motion for judgment as a matter of law on the reverse doctrine of equivalents is denied as moot.

6. Invalidity of Claim 25 of the `370 Patent and Claim 21 of the `312 Patent

BSC moves for judgment as a matter of law that claim 25 of the `370 patent and claim 21 of the `312 patent are invalid for failure to comply with the written description requirement because the specifications disclose only "ring" stents whereas the claims refer broadly to a "stent" and "stent structure." See Tronzo v. Biomet, 156 F.3d 1154, 1158-59 (Fed. Cir. 1998) (holding that unless disclosure suggests to one skilled in the art that broader, more generic invention is necessarily part of disclosure, claims directed to broader invention are invalid for failure to comply with written description requirement). See also Wang Labs., Inc. v. America Online, Inc., 197 F.3d 1377, 1383 (Fed. Cir. 1999). BSC also argues that the claims are invalid because they fail to claim "rings," which are an essential feature of the invention. See Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1480 (Fed. Cir. 1998) (holding that if patent applicant has made clear that particular feature is essential to underlying invention, that feature may not be omitted from claims without violating written description requirement). See also Johnson Worldwide Assoc., Inc. v. Zebco Corp., 175 F.3d 985, 993 (Fed. Cir. 1999).

The court finds that the jury reasonably concluded that the `312 and `370 patent specifications disclose two separate and distinct attributes of a stent - circular rings for radial strength and undulating structures for longitudinal flexibility. At trial, Dr. Tim Fischell stated that the inventors' goal was two-fold:

> . . . . our basic concepts at the time were to make a stent that would be very strong when

> expanded . . . . But also, to make a stent that would be very flexible. . . .

(*D.I. 196 at 526-27) Dr. Buller also described the Fischells' invention as follows:

> . . . their invention was two different things. One component of their invention was trying to go to close to perfectly circular rings, to support the lumen.... And the other component of their invention was undulations within longitudinal structures, to actually bring about even better flexibility within the design of a stent.

(*D.I. 197 at 818-19) Furthermore, the specifications describe the benefits of undulating structures in general terms that are applicable to any kind of stent:

> A stent such as stent 10 could have two or more undulating longitudinals. Such a stent would bend more easily during insertion into a vessel and would be more readily adaptable for placement in curved vessels such as some coronary arteries.

(`312 patent, col. 3, lns. 45-49; `370 patent, col. 3, lns. 46-50)

Because claims 25 and 21 disclose "undulating" structures which are reasonably considered to be one of two separate features of the invention disclosed by the `312 and `370 patents, BSC's motion for judgment as a matter of law that the claims are invalid for failure to comply with the written description requirement is denied.

C. Damages

Upon a finding of infringement, the patent laws permit an award of damages adequate to compensate the patentee for infringement, but in no event less than a reasonable royalty. See 35 U.S.C. § 284. To recover lost profits, "a patent owner must prove a causal relation between the infringement and its loss of profits." BIC Leisure Prods., Inc. v. Windsurfing Int'l. Inc., 1 F.3d 1214, 1218 (Fed. Cir. 1993). In other words, the burden rests on the patentee to show a reasonable probability that "but for" the infringing activity, the patentee would have made the infringer's sales. Water Tech. Corp. v. Calco Ltd., 850 F.2d 660, 671 (Fed. Cir. 1988). To prove entitlement to lost profits, the patentee must demonstrate, inter alia, an absence of non-infringing alternatives, and that it possessed the marketing capacity to make the lost sales. See Rite-Hite, 56 F.3d at 1545 (citing Panduit, 575 F.2d. at 1156); Smithkline Diagnostics Inc. v. Helena Labs. Corp., 926 F.2d 1161, 1165 (Fed. Cir. 1991) (citing Panduit, 575 F.2d at 1156). For those infringing sales for which a patentee cannot establish an entitlement to lost profits, damages in the form of a "reasonable royalty" are required. A reasonable royalty is the amount that a person desiring to manufacture, use or sell a patented article, as a business proposition, would be willing to pay as a royalty and yet be able to make, use or sell the patented article in the market at a reasonable profit. See Wang Labs. v. Toshiba Corp., 993 F.2d 858, 870 (Fed. Cir. 1993) (citation omitted). When an established royalty does not exist, a reasonable royalty may be determined based on "hypothetical negotiations between [a] willing licensor and [a] willing licensee" at the time that the infringement began. Id. (citation omitted). Although a "trier of fact must have some factual basis for a determination of a reasonable royalty," consideration of a hypothetical negotiation "necessarily involves an element of approximation and uncertainty."

Unisplay, S.A. v. Am. Elec. Sign Co., 69 F.3d 512, 517 (Fed. Cir. 1995).

Because the court finds that Cordis is estopped from asserting equivalence of the "plurality of slots formed therein" limitation of claims 23, 51 and 54 of the `762 patent and claims 1 and 3 of the `984 patent, the parties' motions regarding the damages portion of the AVE trial are moot, and BSC's motion for a new damages trial is granted so that the AVE stents may be considered as non-infringing alternatives to the NIR stent.

VI. UNENFORCEABILITY

A. Findings of Fact, Pursuant to Fed. R. Civ. P. 52(a)

1. The `762 Patent

1. **Contention**. AVE and BSC contend that the `762 patent is unenforceable because the patentee committed inequitable conduct by presenting false and misleading arguments to distinguish Ersek during the first reexamination of the parent `665 patent and during the `762 reexamination.

2. **Facts of record**. In his 1983 monograph entitled "Expandable Vascular Endoprosthesis," Dr. Palmaz described the slotted tube configuration as follows:

> The tube could initially be a thin walled silver, tantalum or stainless steel continuous tube in which alternating fissures such as shown in Fig. 1 have been done. This process may require sophisticated techniques such as electronic or laser etching. After expansion,

> the unfolded "bars" between fissures will twist and loss of length will result. Although the expanded tube wall will be thicker than the wire mesh tube the unexpanded tube wall will be smoother and thinner therefore allowing an easier introduction and positioning before inflation.

(PX 1557 at 6) (emphasis added)

3. The `665 patent was filed in November 1985. Although Figures 2A and 2B appear to be smooth, none of the claims of the original `665 patent address this feature. (PX 1)

4. The `762 patent was filed in November 1986. Figures 1A and 1B show smooth first and second diameters, and original claim 23 expressly calls for a smooth first diameter. The second diameter is described in the specification as "relatively smooth." (PX 3, col. 7, lns. 41-45)

5. The early prototypes of the slotted tube invention were rigid and resulted in distortion and twisting upon expansion. (D.I. 1052 at 266-67; D.I. 1054 at 617) The distortion was minimized when an annealing process was applied to the devices. (D.I. 1054 at 652)

6. The `665 patent was submitted for reexamination in 1991, after Ersek was found. (PX 8, Tab 7; PX 12, Tab 6 at 1463) Claim 13 of the `665 patent was amended to include a "tubular shaped member having a second, expanded diameter and a substantially smooth outer

wall surface." (PX 9, Tab 73 at 2184) The examiner initially rejected the amendment because,

> as the Palmaz graft (each embodiment) is expanded and the openings 82 are widened, the forces acting on the graft are similar to that described in Ersek in col. 2, lines 63-75 and col. 3, lines 1-6. The Palmaz elongated members 75, 76 would inherently twist so that the narrow edges of the Figs. 2A, 2B bars, for example, would face outwardly and thus preclude the outer surface from fairly being characterized as "smooth" or "substantially smooth."

(Id., Tab 68 at 2149)

7. In response, the patentee submitted the declaration of John S. Kula, dated March 11, 1993. In his declaration, Mr. Kula averred that, "[w]hen the graft/prosthesis of the Palmaz `665 Patent is expanded to its maximum design specification diameter, the outer wall surface of the graft/prosthesis remains substantially smooth." (Id., Tab 81 at 2252) (emphasis added) The examiner, in allowing amended claim 13 over Ersek, relied on the Kula declaration as evidence "that the elongated members 75, 76 of the embodiment of figs. 2A and 2B of the Palmaz `665 patent do not inherently twist when the graft is expanded." Therefore, the "outer surface of the graft shown in the Palmaz `665 patent is smooth." (Id., Tab 89 at 2282) The examiner also relied on his examination of PX 3986 and PX 3987, models of the Palmaz and Ersek stents, respectively.[23] (Id.)

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[23] The aspect ratio (the ratio of the width of the strut to the strut's thickness, in the cross-section) of the Palmaz peripheral stent (PX

8. Ersek also was reviewed during the course of the `762 reexamination, filed in October 1997. (PX 12) In comparing dependent claim 23 of the `762 patent to Ersek, the patentee declared:

> The Ersek fixation sleeve does not have a substantially uniform wall thickness, nor is it thin walled. The expanded metal sleeve is twice as thick in some areas as in others, and the thickness of the wall varies throughout. The fixation sleeve is deliberately formed to provide a multitude of narrow projecting edges (Figure 5) that are intended to embed themselves into the tissue wall upon expansion of the sleeve. These sharp metal projecting and penetrating edges are a fundamental requirement for the successful operation of the fixation sleeve. Thus, the periphery of the Ersek sleeve is rough, sharp, and not smooth.

(PX 13, Tab 37 at 3079; see also Id., Tab 36 at 3049-50; PX 12, Tab 4 at 1416, 1436)

9. The examiner ultimately allowed claim 23, finding that

> the outside of the wall surface of the Ersek (3,657,744) fixation sleeve is not considered to be smooth. The Ersek fixation sleeve is

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3986) was 1.15, in contrast to the Ersek model's aspect ratio of 4.87 (PX 3987). (D.I. 1052 at 48-49)

> formed of expanded metal. A sample of conventional expanded metal was shown to the examiner during the July 8, 1998 interview. The sample is depicted in Exhibit 1 of the July 22, 1998 amendment. The sample has the same basic shape as that shown in figure 5 of Ersek. As one follows the outside surface of one of the strands of the sample, one meets an abrupt obstacle at the bridge (at the junction of the strands) since the bridge has a thickness which is twice as great as the strand. The outside of the wall surface of the Ersek fixation sleeve includes a multitude of these obstacles (one at each bridge), making it rough rather than smooth. Therefore, the Ersek reference fails to meet the smooth surface limitation quoted above. Further, making the outside of the Ersek fixation sleeve smooth rather than rough would be contrary to the teachings of Ersek since the rough surface formed by narrow outwardly projecting edges is intended to embed itself into the tissue wall upon expansion of the sleeve (col. 3, lines 1-6).

(PX 14, Tab 58 at 3258)

10. According to the evidence of record, some degree of twisting is inherent in the design of the Palmaz and Palmaz-Schatz slotted tube stents upon the application of torsional force. The degree of twisting will depend on a number of factors, including the aspect ratio selected by the designer and the extent of expansion exercised by the cardiologist. (D.I. 1052 at 24-46, 68-69, 143-44, 214, 227-35, 280-85; D.I. 1053 at 358, 367-68; D.I. 1054 at 625-28, 659-60; PX 3989-A) With respect to the former factor, a

large aspect ratio will show a greater degree of twisting for a given amount of expansion force. (D.I. 1052 at 48-49) With respect to the latter factor, the greater the expansion, the greater the tendency to twist. (Id. at 68-69) Cardiologists tend to overexpand the Palmaz and Palmaz-Schatz stents in order to take into account the recoil characteristics of such stents and to secure the stents in the vessels by embedding.[24] (D.I. 1052 at 44-45, 236-38; D.I. 1054 at 685-86) Therefore, even when these factors (aspect ratio, degree of expansion) are controlled, some degree of twisting can be detected in the Palmaz and Palmaz-Schatz stents, to wit: some struts of the stent will be twisted, some will not be, some will be twisted more than others. (D.I. 1052 at 39, 227-31) The twists, however, are "very, very small." (Id. at 27)

11. The record demonstrates that twisting is a desired feature in the Ersek fixation sleeve (the resulting "narrow projecting edges" are intended to embed themselves into the tissue wall upon expansion of the sleeve). In contrast, twisting is an undesired feature of the expanded Palmaz and Palmaz-Schatz stents, as twisting causes "microturbulence" and damage to the arterial wall which increase the risk of thrombus formation and of restenosis. (D.I. 1054 at 648-49, 690-91)

12. The clinical experience with the Palmaz and Palmaz-Schatz stents is not consistent with any significant degree of twisting, as they have performed well with low

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[24] In contrast to the Ersek device, the edges of which must penetrate the tissue of the wall in order to function as designed (not to expand a lumen, but to replace a surgeon's sutures), the struts of the Palmaz and Palmaz-Schatz stents are ultimately "buried" on all three sides by the tissue of the lumen due to the pressure of expansion. (D.I. 1054 at 661, 744-47)

restenosis rates. (D.I. 1052 at 277-79; D.I. 1054 at 648-49, 690-91)

13. By the early 1990s, Dr. Palmaz did not believe that the struts of the Palmaz and Palmaz-Schatz stents "inherently twisted" but believed, instead, that the surface of said stents, as expanded, was "substantially smooth." (D.I. 1054 at 656-60)

2. The `984 and `332 Patents

14. **Contention**. AVE and BSC contend that, during the prosecution of the `417, `984 and `332 "connected stent" patents, the patentees concealed and misled the United States Patent and Trademark Office ("PTO") regarding material "connected Z stent" art.

15. **Facts of record**. Dr. Palmaz became aware of connected Z stents in the mid-1980s and followed the work thereafter. (D.I. 1053 at 565-67) Dr. Schatz began working with Dr. Palmaz in the summer of 1985, (D.I. 1054 at 699) Starting in 1985, Dr. Palmaz shared with Dr. Schatz and with their counsel, Ben D. Tobor, articles on stenting. (Id. at 662-63, 699) By 1988, Mr. Tobor knew of the existence of journals such as Radiology and knew where he could access information for patent prosecution searches. (D.I. 1053 at 600) By the late 1980s, stent research had progressed to the point where research papers were presented by the character of the stent, as opposed to all stent research being grouped together. (Id. at 567)

16. **The `417 patent**. The application for the `417 patent was filed in March 1988. (PX 15, Tab 7) On

March 26, 1988, Dr, Palmaz acknowledged his duty to disclose material information of which he was aware to the patent examiner. (Id., Tab 9)

17. In response to an office action rejecting claims 1-24 (Id., Tab 11), Mr. Tobor argued in February 1989 that:

> Applicant would agree with the Examiner's reasoning and basis for rejection if independent Claims 1 and 17 did not include the method step of "disposing at least one connector member between adjacent prostheses to flexibly connect adjacent prostheses to each other." This step, and claim limitation, does not read merely on "adding additional prosthesis" as contended by the Examiner, but requires some physical connection between discrete prostheses or intraluminal grafts, the physical connection being "at least one connector member." Thus, the issue is not whether or not it would be obvious to use a plurality of prostheses or intraluminal grafts, but whether or not it would be obvious to practice a method, which not only uses a plurality of prostheses, or grafts, but also physically connects adjacent prostheses, or grafts to one another with a connector member.
>
> To illustrate this issue, Applicant would call Examiner's attention to U.S. Patent No. 4,580,568, issued April 8, 1986, in the name of C. Gianturco, for a percutaneous endovascular stent method for insertion

thereof. . . . With respect to the Gianturco `568 patent, this patent teaches the use of a plurality of prostheses or stents, as shown in FIGS. 7 and 8. Applicant would agree that this patent provides a teaching of the use of multiple stents although Applicant seriously questions its efficacy and operability when using multiple stents. However, this is not to say that Gianturco provides a teaching or suggestion of Applicant's methods wherein a connector member is disposed between adjacent prostheses, stents, or intraluminal grafts.

The extensive number of references cited against Applicant's prior patents were virtually all brought to the attention of the prior Examiner by Applicant, and virtually all of the cited references relate to stents, prostheses, or intraluminal grafts. To the best of Applicant's knowledge, and the knowledge of the undersigned counsel, other than the Gianturco `568 patent, none of the other cited references in the Palmaz `762 and `665 patents utilize a plurality of stents, grafts, or prostheses in the methods disclosed in those patents and publications. But for the Gianturco `568 patent, it would appear that the art teaches away from using more than one prosthesis. With the Gianturco `568 patent, Applicant submits that the most that can be said is that one patent teaches the use of a plurality of stents; however, the stents are not connected by a connector member, nor are the plurality of stents inserted into the body

> passageway at the same time as in Applicant's method.

(PX 15, Tab 15 at 81-83; see also id., Tab 33 at 152)

18. By February 1989, multiple journal articles had been published regarding connected Z stents. (See PX 3207; AVEX 364; AVEX 359; AVEX 438; AVEX 671; AVEX 1953) At least one such article (PX 3207) was cited as a reference in a January 1988 article for which Drs. Palmaz and Schatz were given credit for authorship. (PX 4049) Dr. Palmaz was aware of these publications. (D.I. 1053 at 587-99)

19. Sometime in 1989, Dr. Palmaz forwarded to Mr. Tobor a copy of Yoshioka (AVEX 438) as a "pertinent reference" regarding a "stent graft idea," not in connection with the `417 patent prosecution. At the time, Dr. Palmaz did not believe that connected Z stent art was relevant to the `417 patent: connected Z stents had a stabilizer bar between the stents to add rigidity (i.e., to keep them in a rigid position and in place after delivery), while the connector of the `417 patented invention added flexibility. (D.I. 1054 at 664-68)

20. In May 1991, Mr. Tobor brought Yoshioka to the attention of the '417 examiner. Mr. Tobor declared that he did not believe the article was prior art, but was bringing it to the examiner's attention "out of an abundance of caution." The article was described by Mr. Tobor as follows:

> The enclosed article to Yoshioka, et al., discloses an arterial endovascular graft constructed by wrapping an expandable nylon

> mesh around a framework of Gianturco self-expanding metallic stents. "Three or four stents were connected in tandem by metallic struts constructed from the same wire."

(PX 15, Tab 48) Dr. Palmaz does not recall reading this declaration, although he may have been aware of the "argument." (D.I. 1053 at 574-81)

21. The `417 patent issued on April 7, 1992. (PX 15, Tab 58)

22. **The `984 patent.** The application for the `984 patent was filed in October 1988. (PX 16, Tab 10) On September 30, 1988, Dr. Schatz acknowledged his duty to disclose material information of which he was aware to the patent examiner. (Id., Tab 11)

23. The `984 patent was assigned to EGP. (Id., Tab 8) Drs. Palmaz and Schatz were two of the three partners of EGP. Although Dr. Palmaz was consulted about background literature and prior art identified in the `984 patent, he believed that it was Dr. Schatz's responsibility to fulfill the duties of full disclosure in connection with the `984 patent. (D.I. 1053 at 562-63)

24. In response to an office action rejecting claims 1-6 (PX 16, Tab 16), Mr. Tobor argued in February 1990 that

> Gianturco, the only reference known to Applicant which teaches the use of a plurality of grafts, or stents, has at most a teaching of

> the use of a plurality of stents; however, the stents are not connected by a connector member, flexible or otherwise, nor is any connector member, such as claimed in the present application, disclosed, taught or suggested.

(Id., Tab 22 at 5231) (emphasis in original)

25. In December 1990, Mr. Tobor brought Yoshioka to the attention of the '984 examiner, stating:

> It is not believed that the enclosed publication is prior art as against the present application in that the publication date of the publication is "October 1988," and the present application was filed October 4, 1988.
>
> This publication discloses an endovascular stent graft consisting of an expandable nylon cylinder supported by a framework of self-expanding stents. "Three or four stents were connected in tandem by metallic struts constructed from the same wire. The first stent was the lead stent, which acted as an anchor for the graft."

(Id., Tab 36)

26. Dr. Schatz testified that he has no independent recollection of knowing about connected Z stent references prior to July 1991. (D.I. 1054 at 706-17; PX 3996)

27. The claims of the `984 patent were allowed in August 1992. (PX 16, Tab 62)

28. **The '332 patent**. The application for the `332 patent was filed in November 1992 as a continuation of the `984 patent. (PX 17, Tab 4) Dr. Schatz resubmitted his September 30, 1988 declaration acknowledging his duty of disclosure. (Id., Tab 5)

29. In March 1993, in response to an office action rejecting claims, Mr. Tobor argued that Yoshioka

> does not disclose the subject matter for which the Examiner relies upon this article. All Yoshioka et al. has to say about connecting stents is that they "were connected in tandem by metallic struts constructed from the same wire." The article does not say how many metallic struts were utilized, where they were connected, their angular disposition, whether or not they were flexible, or any other details of construction. . . .
>
> Assuming that Yoshioka et al. can be used as a reference, the rejection is still deficient for the following reasons. Neither Wiktor nor Yoshioka et al. discloses a plurality of "thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis

> of each tubular member" and "only one connector member being disposed between adjacent tubular members to flexibly connect the adjacent members." . . .
>
> In summary, with respect to the rejection based upon Wiktor and Yoshioka et al., assuming Yoshioka et al. is properly available as a reference, neither of these references discloses the particular claimed tubular members which are flexibly connected by only one connector member as claimed by Applicant.

(Id., Tab 11 at 2845-46)

30. In October 1994, in connection with Patent Interference No. 103,432, Mr. Tobor argued that the claims of United States Patent No. 5,104,404, filed in June 1991 (the "Wolff patent") were unpatentable over Yoshioka:

> Yoshioka discloses a plurality of tubular shaped stents formed of stainless-steel wire, wherein "three or four stents were connected in tandem by metallic struts constructed from the same wire" as shown in Fig. 1. As seen in Fig. 1 of Yoshioka, a single wire is disposed between the stents to "hinge" the stent segments together. Accordingly, Yoshioka clearly anticipates all of the claims of the Wolff `404 Patent which correspond to Count 1.

(BSCX 6759 at 2-3) The Wolff patent describes, e.g., a number of stents connected together by hinges (the hinges

can be either straight or coiled wire) welded in place to provide articulation between the stent segments.

31. On March 21, 1996, Dr. Schatz submitted a declaration in connection with Patent Interference No. 103,432 regarding Yoshioka:

> I have been informed that this article was publicly available prior to October 1988.
>
> Based upon my review of and study of the Yoshioka article and based upon my extensive experience in the design, testing and use of various stents, including the stents of Schatz Exhibit No. 1 and the `667 application and those of Schatz Exhibit No. 3, it is my opinion that the Yoshioka article; Schatz Exhibit No. 11, teaches, discloses, and describes an articulated self-expanding separate stent comprising at least two stent segments, each stent segment having a generally tubular shape . . ., and a hinge means extending between and connecting adjoining stent segments, whereby the stent segments may flex and articulate about said hinge means to provide support for curved blood vessels.

(PX 106 at 8-9) At the time Dr. Schatz submitted this declaration, he "assumed" that the bar connecting the two Z stents was flexible. (D.I. 1054 at 117-19) Dr. Palmaz never agreed with the above description. (Id. at 684)

32. On December 2, 1998, Mr. Tobor presented new independent claims 26, 37 and 46 that were "specifically drafted to cover certain commercial competitive

products[25] and to avoid the issues of patentability raised during" Interference No. 103,432. (PX 17, Tab 32 at 2933-34) In this submission, Mr. Tobor addressed the "prior art and other materials identified and discussed during interference No. 103,432," including Yoshioka. (Id. at 2936-39) Specifically, Mr. Tobor distinguished the connected Z stent references as follows:

> As the Examiner is well aware, it is improper to combine references unless there is some teaching or suggestion in the prior art for the contemplated combination. . . .
>
> During the above mentioned interviews, Examiner Brittingham recognized the differences between balloon expandable stents, like those of the present application, and self-expanding stents, like those of the connected Gianturco Z-stent publications, and expressly acknowledged that it would be improper to combine references relating to self-expanding stents with references relating to balloon expandable stents, because of such differences.
>
> There is clearly no teaching or suggestion to combine either the self-expanding stents disclosed in the connected Gianturco Z-stent publications or the coiled wire stent disclosed in the Wiktor patent with the stents disclosed in the Palmaz patents in a manner that would create the structures defined in claims 26, 37

[25] Certain of claims 26-36 were intended to cover AVE's MicroStent II and GFX stents, while certain of claims 46-54 were intended to cover BSC's NIR stent. (PX 17, Tab 32 at 2940)

> and 46. The sole basis for any such combination is impermissible hindsight gleaned from applicant's disclosure of his invention. At the time of the invention, there was no suggestion or teaching to interconnect a plurality of balloon expandable, plastically deformable segments as defined in the claims in a manner that would permit the segments to be displaced at an angle with respect to the longitudinal axis of an adjacent segment when the stent is delivered through a curved portion of an access or coronary artery.

(Id. at 2942-43)

33. The claims of the `332 patent were allowed on December 22, 1998. (PX 17, Tab 37)

3. The `312 and `370 Patents

34. **Contention.** BSC contends that, during the prosecution of the `312 patent, the patentees failed to disclose a reference they knew, or should have known, would have been material to the PTO's consideration of the patent application.

35. **Facts of record.** The application for the `312 patent was filed in February 1994 by Robert R. Fischell, David R. Fischell, and Tim A. Fischell. (PX 5003, Tab 9.) Dr. Robert Fischell began working on the invention of the `312 patent in 1993 and, at that time, began collecting articles and patents about stents. (D.I. 1054 at 825, 843-46) Initially, Dr. Fischell prosecuted the patent himself. (PX 5003, Tab 9) At the time the `312 application was filed, Dr. Fischell bad personally prosecuted more than twenty patents

and was fully aware of the duty of disclosure. (D.I. 1054 at 830-31)

36. Only claim 8 of the `312 patent as originally filed mentioned longitudinals having an undulating shape. (PX 5003, Tab 8 at 26) By March 1995, amended claims 24, 26 and 27 described longitudinals having "an undulating shape" or "an undulating structure." (Id., Tab 20 at 66-67) The undulating feature was considered an important way of distinguishing the prior art. (D.I. 1054 at 838; *D.I. 196 at 526-27; *D.I. 197 at 818-19)

37. On July 17, 1995, the attorney prosecuting the European counterpart to the `312 patent, Morton J. Rosenberg, forwarded to Dr. Fischell the "Search Report from the European Patent Office." Mr. Rosenberg noted that

> the only reference which is stated as being particularly relevant to Claim 1 is European Patent Application #579523 whose inventor is Jean-Claude Sgro. We have made a Patentee Search to determine whether we have any corresponding patent in the United States but have come up negatively. It may pay us to make a translation from the French to determine if this is relevant.

(BSCX 11021)

38. As was the case with the original `312 application, the only claim in the European application which mentioned undulating longitudinals was claim 8. (BSCX 11413)

39. In addition to the Sgro reference, among the references mentioned in the European search report and forwarded by Mr. Rosenberg to Dr. Fischell was United States Patent No. 4,856,516 (the "Hillstead patent"), which was noted as a "Y" reference relevant to claim 6. (BSCX 10003, 10004) A "Y" reference is a reference that is particularly relevant if combined with another document of the same category. (D.I. 1055 at 959-64)

40. The Hillstead patent is directed to a stent constructed as described in claim 1 of that patent:

> A stent for reinforcing a vessel within a subject comprising a cylindrical support dimensioned to fit within an interior of said vessel constructed from an elongated wire bent to define a series of relatively tightly spaced convolutions or bends, said wire also bent in the form of a plurality of loops spaced along an axial dimension of the stent and connected by a series of half hitch junctions where each of the plurality of loops includes a number of said regularly spaced convolutions around its circumference, said stent being radially expandable from a first outer diameter which fits within said vessel to a second increased diameter which contacts an inner wall surface of said vessel to reinforce said inner wall.

(PX 5313, Ex. D, col. 4, lns. 37-50; BSCX 10045) According to the specification, the "resultant structure has a high degree of flexibility." (PX 5313, col. 2, ln. 21) Reproduced below is Figure 2A, displayed on the cover page of the Hillstead patent.

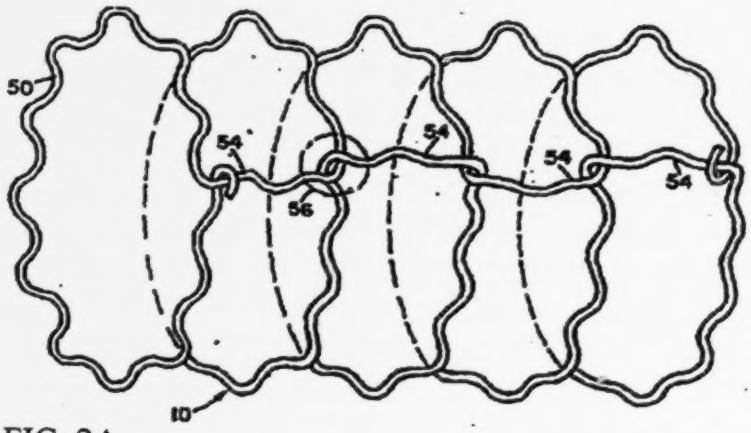

FIG. 2A

41. In December 1995, Dr. Fischell saw stents with undulating longitudinals at the Thorax Center Conference in Rotterdam. His exposure to such stents "heightened (his) perception of the value of claims on undulating longitudinal structures for stents because they enhance flexibility." (D.I. 1054 at 855-57)

42. Also in December 1995, the PTO informed Dr. Fischell that the file wrapper for the `312 patent application could not be located. (PX 5003, Tabs 22, 23) Dr. Fischell himself and through his newly hired attorney, Mr. Rosenberg (Id., Tab 25), submitted a duplicate file that had been maintained by Dr. Fischell. (Id., Tabs 21, 24) When the application submitted in the duplicate file (Id.,*Tab 8 at 24) is compared with the original application (preserved by the PTO on microfilm), there is a difference of one sentence (emphasized below) contained in the latter and omitted from the former:

> It is further anticipated that a pre-deployment stent structure 20 as shown in FIG. 9 could be formed from a thin-walled cylindrical tube

> whose inside diameter is slightly smaller than the outside diameter of the balloon 6 shown in FIG. 6. A pattern such as that shown in either FIG. 6 or FIG. 7 could be photoetched onto a thin-walled metal cylinder. The one piece structure 20 shown in FIG. 9 has folded ovals 22 and longitudinals 23T, 24B, 24R and (not shown) 24L. This pre-deployment stent structure 20 could then be mounted onto the expandable balloon; the stent having sufficient elastic recoil to firmly grasp down onto the balloon. Another method to form the pre-deployment stent is by etching the correct pattern onto a thin, flat metal plate, then forming a tube from that plate and then making a longitudinal weld to form a cylindrically shaped structure which is, in fact, the pre-deployment stent structure 20 shown in FIG. 9.

(BSCX 12011 at 9) (emphasis added) As it happens, the NIR stent is made according to the method described in the emphasized language above.

43. In March 1996, the Fischells, through their company, IsoStent, Inc., entered into a collaboration agreement with Johnson & Johnson whereby Johnson & Johnson would fund IsoStent's stent development and would receive an option to buy IsoStent for more than $20 million. (D.I. 1054 at 854) By March 1996, the Fischells had decided they wanted the claims of the `312 patent to cover all stents with undulating longitudinals, whether such stents had rings or not. (Id. at 857-58)

44. In June and July of 1996, the patentees filed a supplementary amendment; an information disclosure

statement, and a list of patents and publications discussed in the information disclosure statement. (PX 5003, Tabs 29, 30 and 31) The supplementary amendment identified new claims 28 and 29 which featured undulating longitudinal structures. (Id., Tab 29 at 80) The references listed in the information disclosure statement were distinguished as not having undulating longitudinals. (Id., Tab 30 at 85-86) The Hillstead patent was not identified in any of these submissions. (Id., Tabs 30, 31)

45. An amendment was filed by Mr. Rosenberg in November 1996. (Id., Tab 36) Claims 1, 13, 15, 21, 22, and 23 were amended to add language requiring that the longitudinals of the stent have an "undulating shape" or an "undulating contour for enhancing longitudinal flexibility." (Id. at 99-102) The applicants distinguished the prior art, including the Sgro reference, on the ground that such art did "not provide for the undulating shape or contour of the 'longitudinals' of the subject Patent Application system." (Id. at 105-106)

46. The `312 patent issued on July 1, 1997. (PX 5003, Tab 1)

47. Through a series of transactions in 1998 and 1999, Cordis corporation acquired certain assets of IsoStent and agreed to assume certain of IsoStent's obligations to the Fischells, including consulting agreements and royalty payments under, inter alia, the `312 patent. (BSCX 10953; D.I. 1054 at 830)

48. Dr. Fischell and Mr. Rosenberg testified that they did not look at the Hillstead patent until April 1998,

despite both having copies of said reference in their respective files since at least July 1995. (D.I. 1054 at 849-50, 882-89, 914-16; D.I. 1055 at 955, 918-80, 995) The evidence indicates that neither took responsibility for conducting a prior art search directed to the added limitation of "undulating" longitudinals, despite their experience in the field and their focus on the limitation.

49. In May 1998, Dr. Fischell identified the Hillstead patent (along with some sixty other references) as relevant prior art in connection with the '370 patent. (D.I. 1054 at 889-90, 921-25; D.I. 1055 at 980; PX 5002, Tab 16 at 191)

B. Conclusions of Law, Pursuant to Fed. R. Civ. P. 52(a)

1. "Applicants for patents are required to prosecute patent applications in the PTO with candor, good faith, and honesty." Molins PLC v. Textron. Inc., 48 F.3d 1172, 1118 (Fed. Cir. 1995). The duty to prosecute patent applications with candor, good faith, and honesty "rests on the inventor, on each attorney or agent who prepares or prosecutes an application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application." Id. at 1178 n.6.

2. "The duty of candor extends throughout the patent's entire prosecution history. In determining inequitable conduct, a trial court may look beyond the final claims to their antecedents. 'Claims are not born, and do not live, in isolation. Each is related to other claims, to the

specification and drawings . . . Land) to earlier or later versions of itself in light of amendments made to it.' . . . Therefore, a breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application." Fox Indus., Inc. v. Structural Preservation Sys., Inc., 922 F.2d 801, 803-04 (Fed. Cir. 1991).

3. A charge of inequitable conduct includes within its scope "affirmative misrepresentation of a material fact, failure to disclose material information, or submissions of false material information, coupled with an intent to deceive." Molins PLC, 48 F.3d at 1178.

4. "A holding of inequitable conduct requires proof by clear and convincing evidence. This proof must include a threshold showing of both materiality and intent to mislead or deceive the patent examiner." Monon Corp. v. Stoughton Trailers, Inc., 239 F.3d 1253, 1261 (Fed. Cir. 2001) (citing Manville Sales Corp v. Paramount Sys., Inc., 917 F.2d 544, 551 (Fed. Cir. 1990)).

5. "Information is 'material' when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent." Molins PLC, 48 F.3d at 1179. A reference will not be considered material if it is not as relevant as that actually considered by the examiner or if it is merely cumulative of the information considered by the examiner. See, id. "Information concealed from the PTO may be material even though it would not invalidate the patent. . . . As stated, the test for materiality is whether a reasonable examiner would have considered the information important, not whether the

information would conclusively decide the issue of patentability." Li Second Family Ltd. P'ship, 231 F.3d 1373, 1383 (Fed. Cir. 2000), cert. denied, 533 U.S. 929 (2001).

6. "Intent" commonly means "a state of mind in which a person seeks to accomplish a given result through a course of action." Molins PLC, 48 F.3d at 1180 (citing Black's Law Dictionary at 810 (6th ed. 1990)). "Intent need not be proven by direct evidence; it is most often proven by a showing of acts, the natural consequences of which are presumably intended by the actor." Id. "For example, intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application." Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997).

7. "If the threshold requirements of materiality and intent are established, "those fact findings are balanced to make the determination whether the scales tilt to a conclusion that inequitable conduct occurred.' '. . . 'The more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and visa versa.' If, however, either materiality or intent is not found, then no further analysis need be performed and unenforceability must be denied.'" Monon Corp., 239 F.3d at 1261 (citations omitted).

8. "It is not inequitable conduct to omit telling the patent examiner information that the applicant in good faith believes is not material to patentability." Allied Colloids, Inc. v. Am. Cyanamid Co., 64 F.3d 1570, 1578 (Fed. Cir. 1995). Disclosure of relevant prior art to the PTO

during the course of another, subsequent patent prosecution "has no bearing on whether [the patentee] acted with deceptive intent during prosecution of the" application at issue. Li Second Family Ltd. P'ship, 231 F.3d at 1381.

9. "Because the adjudication of an inequitable conduct claim is an equitable determination, it is committed to the discretion of the trial court." Monon Corp., 239 F.3d at 1261.

10. **The `762 patent.** The court concludes that AVE and BSC have not carried their burden of proving by clear and convincing evidence that the patentee intended to deceive the PTO concerning a material fact. The "material fact" identified by AVE and HSC is that the struts of the Palmaz and Palmaz-Schatz stents "inherently twist." The patent examiner, however, started from that premise. The question before the court, therefore, is whether the submissions made by the patentee in response to the examiner's premise were materially false and meant to be so. The court finds neither to be the case. As evidenced by. the record, whatever small degree of twisting that occurs upon expansion of the Palmaz and Palmaz-Schatz stents is meant to be minimized (as distinguished from the Ersek reference) and has been minimized by engineering and production solutions. The patentee believed at the time of the submissions, and continues to believe, that the outer surface of the Palmaz and Palmaz-Schatz stents is "substantially smooth" in the second diameter. Therefore, the threshold levels of materiality and intent have not been demonstrated by clear and convincing evidence. Even had AVE and BSC carried their burden of proof, it is the court's equitable judgment that the patentee's conduct was not so culpable that the `762 patent should not be enforced.

11. **The `984 and `332 patents.** The court concludes that AVE and BSC have not carried their burden of proving by clear and convincing evidence that the patentee failed to adequately disclose material information -- the connected Z stent art -- to the PTO and intended to deceive the PTO in this regard. There is no question but that the connected Z stent art was before the PTO in all three related patents -- the `417, the `984 and the `332 patents -- before any of the patents issued. Although the patentee could have brought Yoshioka or a similar reference to the attention of the PTO earlier than he did, nevertheless, the PTO had the opportunity to consider the prior art before allowing any of the claims at issue. The fact that the patentee's arguments changed[26] over time does not demonstrate (in the court's view) an intent to deceive. Once again, even had the threshold levels of materiality and intent been demonstrated by clear and convincing evidence, in weighing materiality and intent, it is the court's equitable judgment that the patentee's conduct was not so culpable that the `984 and `332 patents should not be enforced.

12. **The `312 patent and `370 patents.** The court concludes that BSC has carried its burden to prove by clear and convincing evidence the threshold levels of materiality and intent with respect to nondisclosure of the Hillstead patent. By the time the `312 patent issued, the patentees considered the most significant invention disclosed in the `312 patent to be undulating longitudinals. The only prior art reference identified in the record that disclosed undulating longitudinals was the Hillstead patent. The patentees purposefully neglected their responsibility of

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[26] Initially, the focus was on whether any prior art disclosed connectors between a plurality of stents. Once such prior art references were found, the focus shifted to the type of connector (flexible or not) and the type of stent (balloon expandable or self-expanding).

candor to the PTO by "putting their heads in the sand" regarding prior art related to their newly added limitation. The court concludes that the threshold levels of materiality and intent have been demonstrated by virtue of the patentees' increasing emphasis on undulating longitudinals during the course of the `312 patent prosecution and the fact that patentees knew, or should have known, that the Hillstead patent would be material to the PTO's consideration of the `312 patent application. The court further concludes that the submission to the PTO of the Hillstead patent during the `370 patent prosecution has no bearing on whether the `312 patentees acted with deceptive intent during the `312 prosecution. The court finds that the `370 prosecution is tainted by the lack of candor exhibited during the `312 prosecution, since the Hillstead patent was submitted along with sixty other references and never addressed by the patentees. In light of all the circumstances, the court concludes that the patentees' conduct was sufficiently culpable that the `312 and `370 patents should be held unenforceable.[27]

VII. CONCLUSION

For the reasons stated, AVE's motion for judgment as a matter of law is granted as to prosecution history estoppel on the "plurality of slots formed therein" limitation of claims 23, 51 and 54 of the `762 patent and claims 1 and 3 of the `984 patent. The parties' motions for a new AVE trial are denied as moot.

BBC's motions for judgment as a matter of law are granted as to prosecution history estoppel on the

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[27] The court finds that BSC has failed to prove by clear and convincing evidence that the "missing sentence" in the `312 application was either material or intended to deceive the PTO.

"substantially uniform thickness" limitation of claim 23 of the `762 patent and no literal infringement of claims 25 and 26 of the `370 patent, and denied as to all other issues. Cordis' motion for judgment as a matter of law against BSC is denied. BSC's motion for a new damages trial is granted.

The court finds that the `762, `984 and `332 patents are enforceable, and the `312 and `370 patents are unenforceable.

An appropriate order shall issue.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civil Action No. 97-550-SLR (consolidated)

CORDIS CORPORATION,
Plaintiff,

v.

MEDTRONIC AVE, INC., BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,
Defendants.

Civil Action No. 97-700-SLR

MEDTRONIC AVE, INC.,
Plaintiff,

v.

CORDIS CORPORATION, JOHNSON & JOHNSON and EXPANDABLE GRAFTS PARTNERSHIP,
Defendants.

Civil Action No. 98-19-SLR

BOSTON SCIENTIFIC CORPORATION,
Plaintiff,

v.

ETHICON, INC., CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,
Defendants.

Civil Action No. 98-197-SLR

CORDIS CORPORATION,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,
Defendants.

ORDER

At Wilmington, this 28th day of March, 2002, consistent with the opinion issued this same day;

IT IS ORDERED that:

1. AVE's motion for judgment as a matter of law (D.I. 1063), and BSC's motion for a new damages trial (D.I. 1069-2) are granted.

2. BSC's motions for judgment as a matter of law (D.I. 992 and D.I. 229 in Civil Action No. 98-197) are granted as to prosecution history estoppel on the "substantially uniform thickness" limitation of claim 23 of the `762 patent and no literal infringement of claims 25 and 26 of the `370 patent, and are denied as to all other issues.

3. BSC's motion for judgment as a matter of law (D.I. 1069-1), Cordis' motion for judgment as a matter of law against BSC (D.I. 1059), and Cordis' motion to supplement the record on inequitable conduct (D.I. 236 in Civil Action No. 98-197) are denied.

4. AVE's motion for a new trial (D.I. 1065), Cordis' motion for a new damages trial (D.I. 1061), and BSC's motion to strike (D.I. 244 in Civil Action No. 98-197) are denied as moot.

5. United States Patent Nos. 4,739,762, 5,195,984, and 5,902,332 are enforceable. United States Patent Nos. 5,643,312 and 5,879,370 are unenforceable.

6. Cordis' motion for permanent injunctions and entry of orders of judgment (D.I. 1084) is denied as to AVE, and denied without prejudice to renew as to BSC upon conclusion of the new BSC damages trial.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civil Action No. 97-550-SLR (Consolidated)

CORDIS CORPORATION, and EXPANDABLE GRAFTS PARTNERSHIP,
Plaintiffs,

v.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.; GUIDANT CORPORATION; ARTERIAL VASCULAR ENGINEERING, INC.; BOSTON SCIENTIFIC CORPORATION; and SCIMED LIFE SYSTEMS, INC.,
Defendants.

Civil Action No. 97-700-SLR

ARTERIAL VASCULAR ENGINEERING, INC.,
Plaintiff,

v.

CORDIS CORPORATION, JOHNSON & JOHNSON, and EXPANDABLE GRAFTS PARTNERSHIP,
Defendants.

MEMORANDUM OPINION

Dated: June 18, 1999
Wilmington, Delaware

ROBINSON, District Judge

INTRODUCTION

Before the court are multiple motions, only some of which are addressed in the memorandum opinion that follows.[1] Plaintiff Cordis Corporation ("Cordis") has moved for entry of a summary judgment of infringement of U.S. Patent No. 5,102,417 (the " `417 patent") by defendant ACS. (D.I. 303)[2] ACS and its parent, Guidant Corporation, have moved for entry of a summary judgment of non-infringement of the `417 patent.[3] (D.I. 306) Defendant Arterial Vascular Engineering, Inc. ("AVE") has moved for entry of a summary judgment of non-infringement on all patents-in suit, which include U.S. Patent No. 4,739,762 (the " `762 patent") and U.S. Patent No. 5,195,984 (the " `984 patent"), as well as the `417 patent. (D.I. 299)

BACKGROUND

As noted above, the patents-in-suit are the '762, the '417, and the `984 patents.[4] The '762 patent is a Continuation-in-part ("CIP") of U.S. Patent No. 4,733,665 ("the '665 patent") and the '417 patent is a CIP of the '762 patent. The '417 and '984 patents have substantially similar disclosures. The '762 patent, filed on November 3, 1986, discloses a single expandable intraluminal graft, and a

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[1] The motions filed by defendants Advanced Cardiovascular Systems, Inc. ("ACS") (D.I. 309) and by defendants Boston Scientific Corporation and Scimed Life Systems, Inc. (D.I. 294) for entry of a summary judgment of invalidity of the `417 patent will be addressed separately.

[2] All docket item references are to C.A. No. 97-550-SLR

[3] At this point in the litigation, ACS' parent, Guidant Corporation, is still a defendant. The two corporations shall be collectively referred to as "ACS."

[4] All the patents-in-suit are reproduced in D.I. 301, Exs. 1-4.

method and apparatus for implanting it. As summarized in the '762 patent,

> [t]he invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraluminal grafts.

('762 patent, Col. 1, lns. 19-25) The specification of the '762 patent describes the expandable intraluminal graft as follows:

> The present invention includes a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall['']s surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; the tubular shaped member having a first diameter which permits intraluminal delivery of the thin-walled tubular member into a body passageway having a lumen; and the tubular member having a second, expanded diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular shaped member may be expanded and deformed to expand the lumen of the body passageway.

* * * * * *

> The method of the present invention comprises the steps of: utilizing a thin-walled, tubular member as the prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member. . . .
>
> * * * * * *
>
> The expandable intraluminal vascular graft, method for implanting a prosthesis within a body passageway, and apparatus for intraluminally reinforcing a body passageway of the present invention, when compared with previously proposed prior art intraluminal grafts, methods for implanting them, and balloon dilation techniques have the advantages of: preventing recurrence of stenoses; is believed to permit implantation of grafts in critical body passageways, such as in the left main coronary artery of the heart; prevents recoil of the body passageway; prevents erosion of the body passageway by the expanded graft; and permits expansion of the graft to a variable size dependent upon conditions within the body passageway.

(`762 patent, col. 3, lns. 34-51; col. 4, lns. 6-11, 62-68 and col. 5, lns. 1-7) (emphasis added).

When the `417 patent application was filed in 1988, an additional problem was addressed.

> For repairing blood vessels narrowed or occluded by disease, or repairing other body passageways, the length of the body passageway which requires repair, as by the insertion of a tubular prosthetic graft, may present problems if the length of the required graft cannot negotiate the curves or bends of the body passageway through which the graft is passed by the catheter. In other words, in many instances, it is necessary to support a length of tissue within a body passageway by a graft, wherein the length of the required graft exceeds the length of a graft which can be readily delivered via a catheter to the desired location within the vascular system. Some grafts do not have the requisite ability to bend so as to negotiate the curves and bends present within the vascular system, particularly prostheses or grafts which are relatively rigid and resist bending with respect to their longitudinal axes.

(`417 patent, col. 3, lns. 5-21; `984 patent, col. 2, lns. 63-68 and col. 3, lns. 1-11) Consequently, the `417 patent, although mirroring the `762 patent, added

> [a] further feature . . . that at least one connector member may be disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members. Another feature of the present invention is that . . . at least one connector member may be disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members. An additional feature of the present invention is that at least

> one connector member may be a thin-walled, spiral member, coplanar with adjacent tubular members.

(`417 patent, col. 4, lns. 8-18) (emphasis added).

The `984 patent, filed in 1991, substituted the following feature for that recited above, that there be a

> single connector member [which] may be a thin-walled, elongate bar member, coplanar with adjacent tubular members. An additional feature of the present invention is that a first connector member may be disposed between the second end of a first tubular member and the first end of a second tubular member; a second connector member may be disposed between the second end of the second tubular member and the first end of a third tubular member; the first and second connector members being angularly offset from one another with respect to the longitudinal axis of the tubular members.

('984 patent, col. 3, ln. 68 and col. 4, lns. 1-10) (emphasis added) .

The disclosure by the `417 and `984 patents of "connector members" added to the invention's advantages by

> permit[ting] tissue of an elongated section of a body passageway to be supported by an elongated graft; and provid[ing] the necessary flexibility to negotiate the bends and curves in tortuous body passageways, such as the vascular system.

(`984 patent, col. 4, lns. 20-25; `417 patent, col. 5, lns. 39-43)

STANDARD OF REVIEW

Summary judgment is appropriate when there is no genuine issue of material fact and the movant is entitled to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986). Facts are considered material only if they might affect the outcome of the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Factual disputes that are irrelevant will not defeat a summary judgment. Id. Likewise, issues are considered genuine only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. Id. If no reasonable jury could find in favor of the non-movant, summary judgment is appropriate. Id. at 249.

Summary judgment is appropriate for non-infringement of a patent. Brenner v. United States, 773 F.2d 306, 307 (Fed. Cir. 1985) (affirming summary judgment of non-infringement). Non-infringement need only be established by a preponderance of the evidence. S. Bravo Sys., Inc. v. Containment Techs. Corp., 96 F.3d 1372, 1376 (Fed. Cir. 1996).

Literal infringement involves a two-step determination: the proper construction of the asserted claims[5] and a determination whether the claims as properly construed read on the accused product or method. Markman

[5] The claim construction, issued separately, is meant to impart a consistent interpretation of common language used in the patents-in-suit, taking into account the specific language chosen by the patentees and the evolution of the inventions as reflected in the specifications.

v. Westview Instruments., Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). To establish infringement of a patent, every limitation set forth in a claim must be found in an accused product or process exactly or by a substantial equivalent. Johnston v. IVAC Corp., 885 F.2d 1574, 1577 (Fed. Cir. 1989). An accused infringer "is entitled to summary judgment, on the ground of non-infringement, by pointing out that the patentee failed to put forth evidence to support a finding that a limitation of the asserted claim was met by the structure in the accused devices." Id. at 1578. Where there is no dispute regarding the structure of the accused device, the infringement issue "collapses to one of claim construction and is thus amenable to summary judgment." Athletic Alternatives. Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1578 (Fed. Cir. 1996).

Even if a product does not literally infringe, infringement may nonetheless be found under the doctrine of equivalents if there is equivalence between the elements of the claim and of the accused product. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997). The doctrine of equivalents is intended to prevent someone from making unimportant and insubstantial changes or substitutions to the patented device. Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950). The test for equivalents must be applied to the individual elements of the claim, not to the invention as a whole. Hilton Davis, 520 U.S. at 29. The analysis under the doctrine is whether the element in the accused device performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claimed element.

ANALYSIS OF ACS AND CORDIS CROSS MOTIONS

The Claims Asserted Against ACS

Cordis has asserted claims 1-3, 9, 11-14, 17, 22, 25, and 29 of the `417 patent against ACS, and presently moves for summary judgment on claim 25. ACS has moved for summary judgment a of non-infringement on all asserted claims of the `417 patent. For purposes of the court's analysis, the claims will be grouped as follows: (1) those claims directed to connecting a plurality of "prostheses," which include independent claim 1 and dependent claims 2-3, 9, 11-14, and those claims directed to connecting a plurality of "intraluminal grafts," which include independent claim 17 and dependent claim 22; and (2) those claims directed to connecting a plurality of "tubular members," which include independent claims 25 and 29. Independent claims 1, 17, 25, and 29 are reproduced below. Claim 1 reads:

> A method for implanting a plurality of prostheses within a body passageway comprising the steps of:
>
> disposing at least one connector member between adjacent prostheses to flexibly connect adjacent prostheses to each other;
>
> disposing the plurality of connected prostheses upon a catheter;
>
> inserting the prostheses and catheter within the body passageway by catheterization of said body passageway; and
>
> providing controllable expansion of at least one of the prostheses at a desired location within the body passageway by expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outwardly into contact with the body passageway, by deforming a portion of the at least one prosthesis with a force in excess of the elastic limit of the portion of the at least one

prosthesis, to implant the prostheses within the body passageway.

(`417 patent, col. 13, lns. 20-40) Claim 17 reads:

A method for expanding the lumen of a body passageway comprising the steps of:
connecting a plurality of intraluminal grafts by at least one flexible connector member disposed between adjacent grafts;
inserting the plurality of connected intraluminal grafts, disposed upon a catheter, into the body passageway until the grafts are disposed adjacent a desired location within the body passageway; and
expanding a portion of the catheter to provide controllable expansion of the intraluminal grafts radially, outwardly into contact with the body passageway, by deforming a portion of the intraluminal grafts with a force in excess of the elastic limit of the portion of the intraluminal grafts, until the lumen of the body passageway at the desired location in the body passageway has been expanded, whereby the intraluminal grafts prevent the body passageway from collapsing and decreasing the size of the expanded lumen, and the intraluminal [g]rafts remain in the passageway.

(`417 patent, col. 14, lns. 39-59) Claim 25 reads:

An expandable intraluminal vascular graft, comprising:
a plurality of thin-walled tubular members, each having first and second ends and a

wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.

(`417 patent, col. 15, lns. 19-40) Claim 29 reads:

An expandable prosthesis for a body passageway, comprising:

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members, of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

(`417 patent, col. 15, lns. 52-68; col. 16, lns. 1-6)

The ACS Multi-Link Stent

The following description of the accused product is taken from the court's earlier memorandum opinion denying Cordis' motion for preliminary relief and is based on the evidence presented in connection with said preliminary proceedings.

The ACS Multi-Link stent is described in ACS literature as comprised of "12 rings linked by 33 articulations for flexibility" (PX 38); "a small latticed stainless steel tube" (PX 52-A); "[c]ut from a tube for optimal radial strength [and having] 33 links for flexibility and conformability" (PX 63). The ACS Multi-Link stent is the commercial embodiment of U.S. Patent No. 5,421,955 (the " `955

patent"), which describes the stent of the invention as generally including

> a plurality of radially expandable cylindrical elements which are relatively independent in their ability to expand and to flex relative to one another. The individual radially expandable cylindrical elements of the stent are dimensioned so as to be longitudinally shorter than their own diameters. Interconnecting elements or struts extending between adjacent cylindrical elements provide increased stability and are preferably positioned to prevent warping of the stent upon the expansion thereof. The resulting stent structure is a series of radially expandable cylindrical elements which are spaced longitudinally close enough so that small dissections in the wall of a body lumen may be pressed back into position against the lumenal wall, but not so close as to compromise the longitudinal flexibility of the stent. The individual cylindrical elements may rotate slightly relative to adjacent cylindrical elements without significant deformation, cumulatively giving a stent which is flexible along its length and about its longitudinal axis but which is still very stiff in the radial direction in order to resist collapse.

(PX 46: `955 patent, col. 1, lns. 59-68; col. 2, lns. 1-12) Beverly Huss, Vice President of ACS' Business Unit, testified that the ACS Multi-Link stent is composed of 12 rings. Each ring is approximately 1.2 millimeters in length, with an expanded diameter that varies from a minimum of approximately 2.5 millimeters up to 4 millimeters. (D.I. 349

at 57) Adjacent rings are connected longitudinally by three links that are 120 degrees apart. Each ring is a "metal strut" defined by "W's and U's," "the center portion of the 'W' represent[ing] the link to the next adjacent ring." (D.I. 169 at 1077-78)

Independent Claims 1 and 17 - Literal Infringement

As recognized by the court, the words "prostheses" and "grafts" are used interchangeably in the `417 patent. (`417 patent, col. 6, lns. 22-33) Therefore, independent claims 1 and 17 both require that "a plurality of prostheses" or "a plurality of intraluminal grafts" be "flexibly connect[ed]" by "at least one connector member. . ." (claim 1) or connected "by at least one flexible connector member. . . ." (claim 17). Consistent with the court's claim construction, both prostheses and grafts have to function; i.e., once either a graft or a prosthesis is "expanded and deformed," it must be capable of "serv[ing] to prevent a body passageway from collapsing . . ." (`417 patent, col. 8, lns. 60-63)[6]

Having concluded that "grafts" and "prostheses" must be functional, the question remains whether Cordis is legally entitled to characterize discrete components of the

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[6] Cordis argues that "[t]he performance characteristic of individual, unconnected grafts [is] not part of the claimed method. . . ." (D.I. 324 at 20) Contrary to Cordis' position, there is nothing in the specification or claim language of the `417 patent to indicate that a "graft" or "prosthesis" can be nonfunctional. Indeed, common sense dictates that a "graft" which does not function as a "graft" cannot be described accurately as a "graft," i.e., its very nomenclature is self-limiting.

ACS Multi-Link stent as a "graft," even though such discrete components are not characterized, produced, marketed, or sold as such by ACS.[7] The court understands that each ACS Multi-Link stent is manufactured as a whole from a hollow tube. (D.I. 300 at 25) Under these circumstances,[8] the court concludes that it is not appropriate to analytically disassemble the whole into some unknown combination of discrete parts in order to find literal infringement. Therefore, defendant ACS' motion for summary judgment as to this issue shall be granted, and plaintiff's motion shall be denied.

Independent Claims 1 and 17 - Doctrine of Equivalents

Cordis has argued that "the Multi-Link's rings - whether viewed singly or in groups of six rings - serve substantially the same purpose as elongated tubular members and function in substantially the same way to achieve substantially the same result." (D.I. 324 at 16) There is conflicting evidence of record as to whether this proposition is true. ACS asserts that 1-2 millimeter rings migrate and lack the mechanical stability to maintain coaxial alignment in the vessel; if so, rings of this size cannot function as grafts or prostheses. (D.I. 167 at 1169; API 68) Cordis proffers evidence to the contrary, that "'stents can range from one millimeter to two centimeters in length.'" (D.I. 324 at 15, citing U.S. Patent No. 5,292,331, col. 5, lns. 28-30) Given this genuine issue of material fact, the court declines to grant either party's motion for summary judgment on the issue of infringement by equivalents.

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[7] According to Cordis' reasoning, one ring or any combination of rings (e.g., two-, three-, four-, or six-ring groupings) could conceivably be viewed as constituting a "graft." (See, e.g., D.I. 324 at 23)

[8] As opposed to where a stent is made up of discrete parts and put together in various combinations, as with the AVE stents.

Independent Claims 25 and 29 - Literal Infringement

Independent claims 25 and 29 of the `417 patent describe the ""expandable intraluminal vascular graft" of claim 25 and the expandable prosthesis" of claim 29 as being comprised of at least two "thin-walled tubular members." The court has construed the term "tubular member" to be, inter alia, a hollow, elongated cylindrical structure with multiple openings formed in its wall surface; the openings likewise must be elongated.[9]

The court, at the preliminary injunction stage, accepted Cordis' contention that each ring of the ACS Multi-Link stent was a thin-walled tubular member flexibly connected to adjacent tubular members. Although the court's claim construction has been revised to some extent, nevertheless, the court concludes that there are genuine issues of material fact as to whether the Multi-Link's rings are long enough to qualify as tubular members, either literally or by equivalents. Therefore, both parties' motions for summary judgment as to these issues shall be denied.

ANALYSIS OF AVE'S MOTION

AVE has moved for summary judgment on all claims asserted against it by Cordis. Specifically, AVE moves for

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[9] Cordis argues that the description of "elongated members" in dependent claims 11 and 12 demonstrates that the "tubular members" need not be elongated. (C.A. No. 97-550, D.I. 324 at 8) Following the principles of claim differentiation as argued by Cordis would require the court to ignore the definitions of "tubular" and of "slot," the evidence cited by the court in its claim construction analysis, and common sense. This the court declines to do.

summary judgment on: 1) claims 1-43 of the `762 patent on the ground that its stents lack the "tubular slotted" limitation; 2) claims 1-36 of the `417 patent on the ground that its stents lack the "connector member" limitation; 3) claims 7, 5-16, 20, 23-24, 27-28, and 31-32 of the `417 patent on the ground that its stents lack the coplanar limitation; 4) claims 9-16 and 22-36 of the `417 patent on the ground that its stents lack the "tubular slotted" limitation; and 5) claims 1-6 of the `984 patent, on the ground that its stents lack the "connector member," "coplanar," and "tubular slotted" limitations. (D.I. 300 at 2)

Description of the AVE Stents[10]

The following description of the AVE stents is taken from the declaration of Matthew J. Birdsall, an engineer currently employed by AVE. (D.I. 296, ¶ 2)

The AVE stents consist of multiple sinusoidal stent elements fused together to form a continuously connected device. The individual AVE stent elements are made from a torus, a circular-shaped object (similar to the inner tube of a bicycle) that has a circular cross-sectional shape. These tori are referred to as "rings" at AVE. After undergoing a heating process, the rings are bent from their normal configuration into a design characterized by a series of peaks and valleys called "crowns."

Upon completion of the bending process, each stent element essentially has its final sinusoidal shape. The

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[10] The AVE stents at issue are sold with AVE's Micro Stent® II ("MSII") and GFX® ("GFX") stent delivery systems. For purposes of the pending motions, the differences between these stents are not significant, and both stents will be referred to collectively as the "AVE stents." (D.I. 300 at 6; D.I. 327, ¶ 4)

sinusoidal shaped stent element (sometimes referred to as a segment) includes a series of curved portions (sometimes referred to as crowns or peaks and valleys) interconnected by substantially straight portions (sometimes referred to as struts).

The stent elements used in the MSII stent delivery system have four upper and lower crowns and a length of 3 mm each, while the stent elements in the GFX stent delivery system have six upper and lower crowns and are 2 mm in length. AVE's stents come in a wide variety of sizes and lengths, which are created by connecting a number of individual 3 mm MSII or 2 mm GFX stent elements together.

To connect the stent elements, they are positioned end to end so that adjacent crowns are in contact with each other. One pair of adjacent crowns is then fused together to form a rigid joint, using AVE's proprietary autogenous laser fusion process. This process is different from a traditional welding process in that no additional material is added to the stent. Instead, existing material from two adjacent crowns is melted and fused together. According to AVE, the sole purpose of the weld is to rigidly connect the flexible stent elements together. There is only one weld between adjacent stent elements, and the stent elements are fused together in a helical manner.

After the autogenous laser fusion process is complete, the distance between the adjacent crowns to be fused together decreases. Although it is still possible to identify (with high magnification techniques) the welded region, there are no discrete sides, facets, faces, or other recognizable geometric features to the welded joints, which have a generally hourglass shape. (D.I. 296 at 3-9)

Tubular Slotted Limitation - Literal Infringement

Consistent with the court's revised claim construction, the AVE stents are not comprised of tubular members having a plurality of slots formed in the wall surface of each tubular member. Therefore, there is no literal infringement of claims 1-43 of the `762 patent, 9-16 and 22-36 of the `417 patent and claims 1-6 of the `984 patent.

Tubular Slotted Limitation - Doctrine of Equivalents

AVE argues that Cordis is precluded from applying the doctrine of equivalents to the accused AVE stents "because required elements are wholly absent from the AVE stents. There is no preexisting structure and no slots formed therein . . . ." (D.I. 300 at 24) Cordis argues that the "AVE slotted tube stent infringes under the doctrine of equivalents because it performs substantially the same function, in substantially the same way, to achieve substantially the same result as the inventive stent." (D.I. 323 at 27)

The analysis to be undertaken in determining equivalence is on an element-by-element basis. The fact that identical elements are absent from the AVE stents does not rule out the presence of equivalent elements. Given the number of claims at issue and the record before the court, the court declines to grant AVE's motion for summary judgment on this issue.

Connector Member Limitation - Literal Infringement

AVE contends that there is no literal infringement of the connector member limitations of the `417 and `984

patents. As previously construed by the court, a "connector member" is a discrete[11] structure disposed or particularly arranged between adjacent grafts, prostheses, or tubular members in order to join them together. AVE urges the court to consider a further limitation to this definition based on the functions ascribed to the connector members by the specifications. Specifically, AVE argues that the connector members must be "elongate" structures.

In support of this argument, AVE cites to the description of the connector member in the `984 patent:

> The cross-sectional configuration of connector members 100, along the longitudinal axis of graft, or prosthesis, 70', is the same, in that connector members 100 have the same uniform wall thickness of elongate members 75 and thus form a thin-walled, elongate bar member 101 which is coplanar with adjacent tubular members 71.

(`984 patent, col. 10, lns. 36-41) (emphasis added)[12] AVE also cites to those portions of the specifications which describe the characteristics of the connector members as they

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[11] "Discrete" has several possible meanings, including "possessed of definite identity or individuality; constituting a separate entity;" "consisting of distinct, unconnected, or unrelated parts; noncontinuous;" "individually distinct but not generally different." Webster's at 647. Of these, the latter is not inconsistent with the concept and function of a "connector member."

[12] Cordis correctly points out that this limitation is described in claims 2 and 5 of the `984 patent, which depend from claims 1 and 4, respectively.

perform their primary function, to flexibly connect adjacent structures:

> Still with reference to FIGS. 7-8, connector members 100 are preferably disposed in a non-parallel relationship with respect to the longitudinal axis of adjacent grafts, or prostheses, 70. Further, it is preferable that the at least one connector member 100 is formed as a thin-walled spiral member 102 which is coplanar with the outer wall surface 74 of the adjacent tubular members 71, or adjacent grafts, or prostheses, 70.
>
> * * *
>
> As seen in FIG. 9, because of the disposition of flexible connector members 100 between adjacent tubular members 71, or grafts, or prostheses, 70, graft, or prosthesis, 70′ is able to flexibly' bend, or articulate, with respect to the longitudinal axis of graft, or prosthesis, 70′, so as to be able to negotiate the curves or bends found in body passageways 80. As seen in FIG. 9, as graft, or prosthesis, 70′ bends, or articulates about the longitudinal axis of graft 70′, the spacing between tubular members 71 increases, or expands, about the outer side of the curve, or bend, 103; and the spacing decreases, or is compressed, on the inner side of the curve, or bend, 104. Likewise, spiral connector members 102 adjacent the outer side of the curve 103 flexibly and resiliently stretch to permit the expansion of the spacing thereat; and the spiral connector members 102 adjacent the inner side of the curve, 104 flexibly and

> resiliently compress to permit the decrease in the spacing between tubular members 71 on the inner side of curve 104. It should be noted that connector members 100 permit the bending, or articulation, of adjacent tubular members 71 in any direction about the longitudinal axis of graft, or prosthesis, 70'.

(`417 patent, col. 12, lns. 7-14, 41-63; see also `984 patent, col. 10, ln. 68 to col. 11, lns. 1-5, 23-32) (emphasis added). In sum, AVE argues that the connector members "must be long enough to provide sufficient spacing between adjacent tubular members to allow them to successfully pass through the bends and curves in the vascular system" and in order to be "capable of having a structural orientation, i.e., of either being parallel or non-parallel to the longitudinal axis of the adjacent grafts or prostheses." (D.I. 300 at 30-31)

In contrast to its portrayal of the patents' connector members, AVE maintains that its "stent elements . . . are autogenously laser-fused . . . to form a rigid, welded joint" and, thus, are not connected by discrete, elongate structures. The word "joint" is defined as "a place where two things or parts are joined or united"; "an area at which two ends, surfaces, or edges are attached." Webster's at 1219. AVE offers a more technical definition, that is, "[t]he surface at which two or more mechanical or structural components are united." (D.I. 300 at 32)

The court declines to add an "elongate" limitation to the phrase "connector member." The phrase as used in the independent claims at issue does not require elongation. Nor does the phrase itself connote any function other than that of connecting. So long as the connecting component is "individually distinct" (i.e., it can be identified as something different from adjacent components), it is discrete.

Therefore, AVE's motion for summary judgment as to this limitation is denied.

Connector Member Limitation - Doctrine of Equivalents

Consistent with the discussion above, the court is not prepared to find, on the record presented, that AVE's welded joints do not perform substantially the same function, in substantially the same way, to achieve substantially the same result as the connector members claimed in the `417 patent and `984 patent.

Coplanar Limitation

Based on the court's claim construction, AVE's motion for summary judgment is denied as to this limitation.

CONCLUSION

For the reasons stated, Cordis' motion for summary judgment is denied, ACS' motion for summary judgment is granted in part and denied in part, and AVE's motion for summary judgment is granted in part and denied in part.

An order shall issue.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Civil Action No. 97-550-SLR (Consolidated)

CORDIS CORPORATION, and EXPANDABLE GRAFTS PARTNERSHIP,
Plaintiffs,

v.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.; GUIDANT CORPORATION; ARTERIAL VASCULAR ENGINEERING, INC.; BOSTON SCIENTIFIC CORPORATION; and SCIMED LIFE SYSTEMS, INC.,
Defendants.

Civil Action No. 97-700-SLR

ARTERIAL VASCULAR ENGINEERING, INC.,
Plaintiff,

v.

CORDIS CORPORATION, JOHNSON & JOHNSON, and EXPANDABLE GRAFTS PARTNERSHIP,
Defendants.

O R D E R

At Wilmington this 18th day of June, 1999, consistent with the memorandum opinion issued this date;

IT IS ORDERED that:

1) Plaintiff Cordis Corporation's motion for summary judgment (D.I. 303) is denied.

2) Defendants Guidant Corporation and Advanced Cardiovascular Systems, Inc.'s motion for summary judgment (D.I. 306) is granted in part and denied in part.

3) Defendant Arterial Vascular Engineering, Inc.'s motion for summary judgment (D.I. 299) is granted in part and denied in part.

02-1457, -1458, -1481, -1482

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CORDIS CORPORATION,
Plaintiff Appellant,

v.

MEDTRONIC AVE, INC.,
Defendant-Cross Appellant,
and
BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,
Defendants.

MEDTRONIC AVE, INC.,
Plaintiff-Cross Appellant,
and
ARTERIAL VASCULAR ENGINEERING, INC.,
Counterclaim Defendant-Appellee,

v.

CORDIS CORPORATION,
Defendant/Counterclaimant-Appellant,
and
JOHNSON AND JOHNSON and EXPANDABLE GRAFTS PARTNERSHIP,
Defendants.

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the CROSS-APPELLANTS, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on October 10, 2003.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civil Action No. 97-550-SLR (consolidated)

CORDIS CORPORATION,
Plaintiff,

v.

MEDTRONIC AVE, INC., BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,
Defendants.

Civil Action No. 97-700-SLR

MEDTRONIC AVE, INC.,
Plaintiff,

v.

CORDIS CORPORATION,. JOHNSON & JOHNSON and EXPANDABLE GRAFTS PARTNERSHIP,
Defendants.

Civil Action No. 98-19-SLR

BOSTON SCIENTIFIC CORPORATION,
Plaintiff,

v.

ETHICON, INC., CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,

Defendants.

Civil Action No. 98-197-SLR

CORDIS CORPORATION,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,
Defendants.

MEMORANDUM ORDER

At Wilmington, this 15th day of May, 2002, having reviewed the parties' motions for reconsideration of the court's opinion and order dated March 28, 2002;

IT IS ORDERED that:

1. BSC's motion for reconsideration of its motion for a new trial on infringement of the "substantially uniform thickness" limitation (D.I. 1130) is granted. Although the prosecution history of United States Patent No. 4,739,762 (the "'762 patent") had been reviewed by the court for purposes of claim construction, the issue of whether the doctrine of prosecution history estoppel precluded Cordis from seeking infringement by equivalence was not submitted by defendants for the court's consideration until trial had commenced. (D.I. 947, 992) Faced with a legal question raised for the first time during trial, the court declined to

submit the question to the jury. BSC argues that the court committed legal error by not submitting to the jury a detailed verdict form that itemized the jury's infringement analysis on a limitation-by-limitation basis. The court finds that it did commit legal error in this regard.

As an initial matter, the court finds that both defendants submitted detailed jury instructions and only accepted the final version of the jury instructions after the court, consistent with Cordis' position, rejected the more lengthy, complicated versions proffered by defendants. Therefore, contrary to Cordis' argument, neither defendant waived its position regarding the proper form of jury verdict.

As to the merits of BSC's motion, the court concludes that BSC is entitled to a new trial on infringement of the "substantially uniform thickness" limitation. As explained by the Federal Circuit in Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449 (Fed. Cir. 1998),

> [a]lthough an appellate court must sustain a jury verdict against a JMOL if there are any reasonable grounds for the verdict, an appellate court must also vacate a jury verdict and remand for a new trial if a jury may have relied on an impermissible basis in reaching its verdict.

Id. at 1465 (emphasis in original) (citations omitted). See also Carden v. Westinghouse Elec. Corp., 850 F.2d 996, 1000 (3d Cir. 1988) ("In our jurisprudence it has been established that a general verdict must be set aside where the jury has been instructed that it could rely on two or more independent grounds or claims and one of those grounds or claims turns out to be insufficient."); Molten Metal Equip.

Innovations, Inc. v. Metaullics Sys. Co., 130 F. Supp. 917, 923 (N.D. Ohio 2001).

In this case, although the court concluded that there was sufficient evidence to support a finding of literal infringement of the "substantially uniform thickness" limitation (thus meeting the JMOL standard), it is possible that the jury relied or the doctrine of equivalents for its finding of infringement of that limitation. Under these circumstances, where the court has found that Cordis is not entitled to any range of equivalents for the "substantially uniform thickness" limitation, it was not harmless error for the court to have given the jury a general verdict form. Therefore, the jury's verdict as to BSC's infringement of claim 23 of the `762 patent is vacated, and a new trial shall be conducted to determine whether BSC has infringed the "substantially uniform thickness" limitation.

2. AVE's motion for reconsideration of its motion for a new trial (D.I. 1131) is granted. Pursuant to Fed. R. Civ. P. 50(c)(1), the court is required to address the merits of AVE's motion for a new trial in the event that the Federal Circuit reverses the grant of AVE's motion for judgment as a matter of law. AVE's motion for a new trial is granted in part and denied in part for the following reasons:

a. "Essence of the Invention" Arguments. AVE argues that it is entitled to a new trial because Cordis improperly compared the AVE stents to the "essence of the invention" of the `762 patent and United States Patent No. 5,195,984 (the "`984 patent") rather than to the asserted claims. The Federal Circuit has stated that it is entirely appropriate to use the "essence of the invention" to describe the doctrine of equivalents. See London v. Carson, Pirie Scott & Co., 946 F.2d 1534, 1538 (Fed. Cir. 1991) ("[T]he patentee should not be deprived of the benefits of his

patent by competitors who appropriate the essence of an invention while barely avoiding the literal language of the claims."); Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1567 (Fed. Cir. 1983) ("Though applicable elsewhere, e.g., in determining infringement under the doctrine of equivalents, there is no legally recognized 'essence' of the invention applicable in determining validity."). Consequently, the court included the following description of the infringement analysis in its charge to the jury:

> On the other hand, the patent owner should not be deprived of the benefits of his patent by competitors who appropriate the essence of an invention while barely avoiding the literal language of the patent claims.

(D.I. 1115)

In the absence of a limitation-by-limitation analysis of the asserted claims and an instruction by the court to perform such an analysis, Cordis' references to the "essence of the invention" would perhaps be misleading to a jury. During the AVE trial, however, Cordis presented a detailed comparison of the asserted claim limitations to the AVE stents through the testimony of Drs. Buller and Collins. (D.I. 960 at 604-719; D.I. 962 at 1255-1305) Furthermore, the court instructed the jury to perform a limitation-by-limitation analysis to determine infringement (D.I. 1115), and the court must presume that the jury followed its instructions. See Jones v. United States, 527 U.S. 373, 401 (1999). Thus, because the court finds that the parties and the court presented the jury with the correct analysis to determine infringement under the doctrine of equivalents and that Cordis' references to the "essence of the invention" were not

prejudicial, AVE is not entitled to a new trial on these grounds.[1]

b. **"Building Block" Arguments.** AVE also contends that it is entitled to a new trial because Cordis compared the AVE stents to the "building block" rather than to the asserted claims of the `762 and `984 patents. "Infringement, literal or by equivalence, is determined by comparing an accused product not with a preferred embodiment described in the specification, or with a commercialized embodiment of the patentee, but with the properly and previously construed claims in suit." SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1121 (Fed. Cir. 1985).

Although the term "building block" does not appear in the patents, a completely half-slotted stent is not inconsistent with the patent claims as construed by the court. Cordis used its "building block" analogy appropriately, that is, in conjunction with a limitation-by-limitation comparison of the patent claims to the AVE stents. Furthermore, the court permitted AVE to respond to Cordis' use of the "building block" analogy through cross-examination, and concludes that AVE was not unduly prejudiced by it.[2] (D.I.

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[1] AVE also contends that Cordis contributed to jury confusion by referring to the "essence" of United States Patent No. 4,733,665 (the `665 patent"), which was not asserted at trial. The court agrees with Cords that testimony regarding the `665 patent was limited to establishing a priority date for the `762 patent, and that any references by Cordis to the "essence" of the `665 patent were not prejudicial or cause for jury confusion.

[2] Because the "building block" analogy was used to illustrate infringement of the `762 patent and not the `984 patent, the court appropriately limited AVE's cross-examination of Dr. Schatz regarding it. (D.I. 962 at 1130-31)

959 at 422-23) AVE's motion for a new trial on this basis is denied.

c. **Lack of a Detailed Verdict form.** AVE contends that a new trial is warranted because the court did not use a limitation-by-limitation verdict form to preclude the jury from finding literal infringement of the "plurality of slots formed therein" limitation pursuant to the court's grant of summary judgment prior to trial, and infringement by equivalence of the "substantially uniform thickness" limitation pursuant to the court's finding of prosecution history estoppel after trial. The court finds that, because Cordis did not present a literal infringement argument regarding the "plurality of slots formed therein" limitation at trial,[3] AVE is not entitled to a new trial on infringement of that limitation. For the reasons stated above regarding BSC's motion for a new trial, however, AVE's motion for a new trial on infringement of the "substantially uniform thickness" limitation is granted in the event that the Federal Circuit reverses the court's grant of judgment as a matter of law.

d. **Verdict Against the Weight of the Evidence.** AVE's motion for a new trial based on the all-inclusive argument that Cordis' various litigation strategies

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[3] Significantly, Dr. Collins specifically stated that Cordis was alleging infringement of that limitation only under the doctrine of equivalents:

> Q. Just to make sure that is clear, I understand you to be saying there is an equivalent. But my question was, AVE's products do not literally have slots formed therein. Correct, Dr. Collins?
>
> A. They do not literally have slots formed therein, given the definition of slots formed therein, but they have an equivalent.

(D.I. 962 at 1334)

caused the jury to disregard the clear weight of the evidence is denied.

3. Cordis' renewed motion for entry of judgment dismissing its claims against AVE on United States Patent Nos. 5,902,332 (the "`332 patent") and 5,102,417 (the "`417 patent") (D.I. 1132) is granted as follows:

a. Cordis' and AVE's claims regarding infringement of claims 1, 3 and 5 of the `332 patent and of claims of the `417 patent are dismissed with prejudice.

b. AVE's claims regarding validity and enforceability of claims 1, 3 and 5 of the `332 patent and of claims of the `417 patent are dismissed without prejudice.

4. Cordis` motion for reargument of the grant of a new BSC damages trial (D.I. 1135) is denied. The court finds that BSC did not unconditionally stipulate that the AVE stents infringed the asserted claims of the `762 and `984 patents.

5. Cordis' motion for reargument of the denial of an injunction against BSC with leave to renew or, in the alternative, for an order under Fed. R. Civ. P. 54(b) directing the entry of judgment on Cordis' claims against AVE (D.I. 1133) is granted in part and denied in part. Because the court granted BSC's motion for a new trial on infringement of the "substantially uniform thickness" limitation, Cordis is not entitled to entry of a permanent injunction against BSC at this time. Because all issues concerning AVE have been finally adjudicated and there is no just cause for delay,[4] the

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[4] An immediate appeal as to AVE may eliminate the need to conduct a retrial on the outstanding issues regarding BSC. Furthermore, an (continued...)

court will enter judgment as to AVE pursuant to Fed. R. Civ. P. 54(b).

6. The retrial of infringement of the "substantially uniform thickness" limitation and damages as to BSC is stayed pending the resolution of the appeal of issues concerning AVE by the Federal Circuit.

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immediate appeal would expedite the resolution of a related case, Cordis Corp. v. Medtronic AVE, Inc., Civil Action No. 00-886-SLR.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civil Action No. 97-550-SLR (consolidated)

CORDIS CORPORATION,
Plaintiff,

v.

MEDTRONIC AVE, INC., BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,
Defendants.

Civil Action No. 97-700-SLR

MEDTRONIC AVE, INC.,
Plaintiff,

v.

CORDIS CORPORATION,. JOHNSON & JOHNSON and EXPANDABLE GRAFTS PARTNERSHIP,
Defendants.

Civil Action No. 98-19-SLR

BOSTON SCIENTIFIC CORPORATION,
Plaintiff,

v.

ETHICON, INC., CORDIS CORPORATION and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,

Defendants.

Civil Action No. 98-197-SLR

CORDIS CORPORATION,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,
Defendants.

JUDGMENT IN A CIVIL CASE

Pursuant to the court's May 15, 2002 order addressing the parties' motions for reconsideration and reargument of the court's opinion and order dated March 28, 2002;

IT IS ORDERED AND ADJUDGED that judgment be and is hereby entered in favor of Medtronic AVE, Inc. ("AVE") and against Expandable Grafts Partnership and Cordis Corporation (collectively, "Cordis") with respect to AVE's infringement of claims 23, 51 and 54 of United States Patent No. 4,739,762 (the "`762 patent") and of claims 1 and 3 of United States Patent No. 5,195,984 (the "`984 patent").

IT IS FURTHER ORDERED AND ADJUDGED that judgment be and is hereby entered in favor of Cordis and against AVE with respect to the validity of claims 23, 51 and 54 of the `762 patent and of claims 1 and 3 of the `984 patent, and with respect to the enforceability of the `762 and `984 patents.

IT IS FURTHER ORDERED AND ADJUDGED that judgment be and is hereby entered in favor of AVE and against Cordis with respect to AVE's infringement of claims 1, 3 and 5 of United States Patent No. 5,902,332 (the "`332 patent") and of claims of United States Patent No. 5,102,417 (the "`417 patent").

IT IS FURTHER ORDERED AND ADJUDGED that, pursuant to Fed. R. Civ. P. 54(d)(1) and D. Del. L.R. 54.1, Cordis shall pay AVE its costs incurred in defending Cordis' claims based on the `762, `984, `332 and `417 patents.

IT IS FURTHER ORDERED AND ADJUDGED that, pursuant to Fed. R. Civ. P. 54(b), there is no just cause for delay in entering judgment in favor of AVE.

Dated: May 15, 2002

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civil Action No. 97-550-SLR
(and Civil Action No. 98-65-SLR consolidated)

CORDIS CORPORATION, and EXPANDABLE GRAFTS PARTNERSHIP,
Plaintiff,

v.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.; GUIDANT CORPORATION; MEDTRONIC AVE, INC.; BOSTON SCIENTIFIC CORPORATION; and SCIMED LIFE SYSTEMS, INC.,
Defendants.

ORDER

At Wilmington this 12th day of October, 2000, having heard oral argument on various summary judgment motions related to infringement and having reviewed the papers submitted in connection therewith; and recognizing that the following legal principles govern these summary judgment proceedings, to wit:

1. Summary judgment is appropriate only "if the pleadings, depositions, answers to interrogatories, and admissions on file, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). "The evidence must be viewed in the light most favorable to the

nonmoving party." Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1575 (Fed. Cir. 1995).

2. In an infringement analysis, "the asserted claims must be interpreted by the court as a matter of law to determine their meaning and scope." Id.

> Arguments and amendments made during the prosecution of a patent application and other aspects of the prosecution history, as well as the specification and other claims, must be examined to determine the meaning of terms in the claims. . . . The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.

Id. at 1576. After the claims have been construed by the court, the trier of fact must then decide "whether the claims as thus construed read on the accused product." Id. at 1575. "To establish literal infringement, every limitation set forth in a claim must be found in an accused product exactly. . . Infringement, both literal and under the doctrine of equivalents, is an issue of fact." Id.

NOW, THEREFORE, based on the court's claim construction (D.I. 790) and the summary judgment papers filed with the court, IT IS ORDERED that:

1. Cordis' motion for reconsideration of the grant of summary judgment to Medtronic AVE on literal infringement of the "slots formed therein" limitation of the '762 and '984 patents (D.I. 792) is denied. The court's revised claim construction (D.I. 790) has no bearing on it prior analysis.

2. Cordis' motion for summary judgment of infringement by Medtronic AVE of claim 23 of the '762 patent and claims 1 and 3 of the `332 patent has been withdrawn. (D.I. 675; D.I. 792) Indeed, Cordis has just filed a motion for entry of judgment in favor of Medtronic AVE on the `332 patent. (D.I. 891)

3. Cordis' motion for summary judgment of infringement by BSC of claim 23 of the `762 patent has been withdrawn.. (D.I. 671; D.I. 792)

4. BSC's motion for summary judgment of noninfringement of claims 23, 51 and 52 of the `762 patent (D.I. 696) is denied, as there are genuine issues of material fact as to whether the wall surface of BSC's NIR stent is "disposed in a common cylindrical plane" and has a "substantially uniform thickness." (Compare D.I. 729 at 14 with D.I. 698, Ex. 4 at 9 and Ex. 5) Likewise, there is a genuine issue of material fact as to whether the wall surface of the NIR stent is "smooth." (Compare D.I. 729 at 17-18 with D.I. 763, Ex. A at 8)

5. Cordis' motion for summary judgment of infringement by BSC of claim 44 of the `762 patent (D.I. 671) is denied, as is BSC's motion of noninfringement (D.I. 696), as there is a genuine issue of material fact regarding the claim limitation of "thin-walled" tubular member. Although the prosecution history could be read to give the same meaning to the claim elements "thin-walled" and "substantially uniform thickness,"[1] the court defined them

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[1] Compare the following:

> "Ersek does not disclose a 'thin-walled' tubular member. The Ersek fixation sleeve has a thickness at the bridge or bond areas that is several times the

(continued...)

differently. Therefore, there is a question of fact for the jury as to whether the NIR stent is a "thin-walled" tubular member.[2]

6. Although the court rejected BSC's narrow claim construction, the court concludes that there remain genuine issues of material fact as to whether BSC's NIR stent infringes, either literally or by the doctrine of equivalents, the elements of claim 22 of the `332 patent. Specifically, the court concludes that a jury should properly consider whether the NIR stent has "segment[s] having a generally tubular shape." (Compare D.I. 679, Ex. 40 at ¶ 27 with D.I. 680, Ex. 64 at 595-96 and D.I. 681, Ex. 72) Therefore, Cordis' motion for summary judgment of infringement by BSC of claim 22 of the `332 patent (D.I. 671) is denied, as is BSC's motion for summary judgment of noninfringement (D.I. 696).

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thickness of the starting material." (D.I. 691, Ex. 36 at PWRAP 003054)

"Clearly, the Ersek sleeve cannot be fairly said to have a wall surface with 'a substantially uniform thickness.' The expanded metal Ersek sleeve has bridge portions that are several times as thick as the strands." (D.I. 691, Ex. 36 at PWRAP 003055)

[2] Under the court's claim interpretation, the NIR stent would comprise a "tubular member having a plurality of slots formed therein."

MOTION FILED

FEB 6 - 2004

(2)

No. 03-963

In the Supreme Court of the United States

MEDTRONIC VASCULAR, INC., PETITIONER

v.

CORDIS CORP., RESPONDENT

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

MOTION OF PUBLIC KNOWLEDGE FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF AND BRIEF OF PUBLIC KNOWLEDGE AS *AMICUS CURIAE* IN SUPPORT OF THE PETITIONER

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February 6, 2004

MOTION OF PUBLIC KNOWLEDGE FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF

Pursuant to Rules 21, 29, 33.1, and 37.2 of the Rules of this Court, Public Knowledge hereby moves for leave to file the accompanying brief as *amicus curiae* in support of the petition for writ of *certiorari* in the above-captioned case. Counsel for the Petitioner has consented to the filing of this brief, and Petitioner's letter has been filed with the Clerk.

Public Knowledge was asked to become an *amicus* on February 2, 2004, only four days before filing of this brief. On February 3, 2004, Public Knowledge contacted counsel for a law firm seeking to have that firm represent it in filing a brief *amicus curiae* in support of the petition for certiorari. In the afternoon of February 4, 2004, said counsel informed Public Knowledge that it could not provide such representation. In the evening of February 4, 2004, the undersigned counsel agreed to draft and file the attached amicus brief on behalf of Public Knowledge. On February 5, 2004, the undersigned counsel contacted counsel for Respondent – after Public Knowledge had determined with the Court that a brief was still timely – to request consent to file the attached brief. Because of the late date, however, counsel for Respondent did not have sufficient time to determine Respondent's position in regard to this filing. Accordingly, counsel for Respondent was obliged to withhold its consent at this time.

Filing of this brief will assist the Court in considering the difficult and important legal issues raised by the petition for certiorari. Public Knowledge is a non-profit advocacy group located in Washington, DC. Undersigned counsel is a professor of patent law at the Washington

College of Law, American University, who has previously filed a brief *amicus curiae* on the merits of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, No. 00-1543, which relates directly to the issues raised by the petition for certiorari. Public Knowledge and undersigned counsel have previously submitted a brief *amicus curiae* at the certiorari stage in *Duke University v. Madey*, No. 02-1007.

Filing of this brief also is in the interests of justice. Public Knowledge and its counsel diligently sought to obtain consent of counsel, Petitioner's counsel granted such consent, and Respondent's counsel did not refuse but could not provide such consent. Public Knowledge has a substantial interest in the outcome of the petition. Public Knowledge's mission is to work to ensure that intellectual property law and policy reflect the proper scope of protection intended by the framers of the Constitution and adopted by the Congress, which promote rather than discourage innovation and competition. Public Knowledge's experience before this Court and in other fora makes it well suited to advocate the important public-regarding concerns that this case and this brief present.

Accordingly, Public Knowledge respectfully requests that the Court grant leave to file the accompanying brief *amicus curiae* in the above-captioned case.

Respectfully submitted,

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February 6, 2004

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Statement of Interest of *Amicus Curiae*

This brief is filed on behalf of Public Knowledge (PK).[1] PK is a non-profit advocacy and education organization that promotes a balanced approach to intellectual property law and technology policy reflecting the "cultural bargain" intended by the framers of the U.S. Constitution. PK works to promote fundamental democratic principles and cultural values of openness, access, and the capacity to create and compete. PK advocates for patent policies and laws that ensure that innovation, creativity, and competition are encouraged. PK believes the "clear and unmistakable" disclaimer standard for finding an argument-based estoppel applied by the Federal Circuit in this case: (1) conflicts with this Court's recent holding in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002); (2) conflicts with other Federal Circuit standards for evaluating whether amendments and arguments narrow patent scope and trigger estoppel, unjustly enriches patentees, and lacks historic justification; and (3) will result in increased uncertainty or scope for virtually every patent, hindering competition and harming the public.

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[1] Petitioner's letter of consent has been filed with the Clerk. A motion for leave to file this brief also has been filed, because Amicus Curiae was unable to request the consent of Respondent in sufficient time to allow Respondent's counsel to determine Respondent's position. This brief was not authored in whole or in part by counsel for any party. No one other than *amicus* and its counsel made a monetary contribution to preparing or submitting this brief.

Summary of Argument

The Court of Appeals for the Federal Circuit in this case applied an unduly restrictive view of when arguments (made by an applicant during prosecution to narrow the meaning of claim language) bar application of the doctrine of equivalents during an infringement action. Under this standard, the disclaimer of equivalents must be "clear and unmistakable." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1358, 1363 (Fed. Cir. 2003). This restrictive standard for estoppel is inconsistent with this Court's recent holding in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002). In that case, this Court explained that amendments made to narrow claim language presumptively trigger estoppel, and articulated standards for rebutting this presumption. There is no principled reason to distinguish between argument-based and amendment-based estoppels. Because applicants may choose whether to submit narrowing arguments or amendments, however, the more restrictive standard for finding an argument-based estoppel invites patentees to evade the *Festo* presumption.

The restrictive "clear and unmistakable" disclaimer standard for argument-based estoppel was recently adopted by the Federal Circuit. The standard conflicts with its current and earlier tests for determining when arguments and amendments narrow claim scope and trigger an estoppel. Application of the new standard will unjustly enrich patentees at the expense of the public, granting protection that they neither sought nor obtained and may not deserve. The new standard lacks historic justification and is incoherent, because it fails to recognize the common origins of claim scope and estoppel principles.

The Federal Circuit's "clear and unmistakable" disclaimer standard will increase the uncertainty of or expand patent scope for virtually every patent issued. Similarly, the standard will cause more and more costly litigation. As a result, competitors may refuse to invent and market goods and services or may charge higher prices for the goods and services that they ultimately offer. In either event, the new disclaimer standard will impose significant public harm.

Argument

I. The "Clear and Unmistakable" Disclaimer Standard Is Inconsistent With This Court's Recent Decision in *Festo* and Invites Evasion of *Festo's* Estoppel Principles.

This Court recently held in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), that narrowing amendments to claim language presumptively estop the patentee from resorting to the doctrine of equivalents to recapture the impliedly disclaimed subject matter in an infringement action. "When the patentee responds to a rejection by narrowing his claims, this prosecution history estops him from later arguing that the subject matter covered by the original, broader claim was nothing more than an equivalent." *Id.* at 727. *See id.* at 737 (by making a narrowing amendment "the patentee [is regarded] as having conceded an inability to claim the broader subject matter or at least as having abandoned his right to appeal a rejection."). Once the presumption applies, the patentee is estopped from asserting the doctrine of equivalents, unless the patentee can meet its burden of

rebutting the presumption in regard to the particular equivalents at issue. *See id.* at 740-41.

Nothing in the Court's dicta or analysis in *Festo* suggests that there should be any difference in treatment when a patentee narrows the meaning of claim language by an argument from when a patentee narrows the meaning of claim language by substituting different terms.[2] Under the Federal Circuit standard applied in this case, however, narrowing arguments made to obtain a patent do not trigger an estoppel unless the disclaimer of claim scope is "clear and unmistakable." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1358, 1363 (Fed. Cir. 2003). Conversely, if the disclaimer is clear and unmistakable, there can be no rebuttal. This new standard impermissibly shifts the burden of proving disclaimer of the equivalents at issue from the patentee to the applicant.

Not only is the "clear and unmistakable" standard inconsistent with *Festo*, it is unwarranted as a matter of traditional patent law principles. As this Court stated in *Festo,* the patentee should not be able to argue for a narrow application of the claim in the U.S. Patent and Trademark Office (PTO or Patent Office) and for a broad application in infringement. "Were it otherwise, the inventor might avoid the PTO's gatekeeping role and seek to recapture in an infringement action the very subject matter surrendered as a condition of receiving the patent." *Festo,* 535 U.S. at 734

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[2] In the context of the "recapture rule" for broadening reissue patents, the Federal Circuit has acknowledged that there is no reason to distinguish between narrowing arguments and narrowing amendments. *See Hester Indus., Inc. v. Stein, Inc.*, 142 F.3d 1472, 1481 (Fed. Cir. 1998) ("Arguments made to overcome prior art can equally evidence an admission sufficient to give rise to a finding of surrender.").

(*citing Goodyear Dental Vulcanite Co. v. Davis,* 102 U.S. 222, 228 (1880)). *See Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (1985) ("the prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance."). *Cf. Sprigg v. Bank of Mount Pleasant,* 35 U.S. 257, 265 (1836) (traditional civil estoppel applies where "a party has, by his own voluntary act, placed himself in a situation as to some matter of fact, that he is precluded from denying it."). Because applicants may choose whether to submit narrowing arguments or amendments, the Federal Circuit's more restrictive standard for finding an argument-based estoppel will invite patentees to evade the *Festo* presumption. Applicants will now submit arguments rather than amendments in the Patent Office, and will further argue in infringement actions that their earlier prosecution arguments were unclear or mistakable.

II. The "Clear and Unmistakable" Disclaimer Standard Conflicts With Related Federal Circuit Standards, Unjustly Enriches Patentees, and Lacks Historic Justification.

This Court has provided little guidance regarding how to determine whether amendments and arguments narrow claim meaning and thus disclaim literal claim scope and presumptively estop equivalents protection. However, the Federal Circuit at an earlier stage clearly established the appropriate standard for doing so. "The legal standard for determining what subject matter was relinquished is an objective one, measured from the vantage point of what a competitor was reasonably entitled to conclude, from the prosecution history, that the applicant gave up to procure

issuance of the patent." *Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 952 (Fed. Cir. 1993). This standard was self-consciously the same standard that the Federal Circuit had applied to determining the scope of claim language in the first instance. *See id.* at 952 n.15. The Federal Circuit en banc subsequently approved of this standard, in a case determining the scope of statutory equivalents of claims drafted in "means-plus-function" claim format under 35 U.S.C. § 112, ¶ 6. *See Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1457 (Fed. Cir. 1998) (en banc) (literal claim scope is to be determined from the perspective of whether "a competitor would reasonably believe that the [patentee] had surrendered the relevant subject matter."). The Court reiterated that the same standard applies to equivalency determinations. *See id.* (*citing Alpex Computer Corp. v. Nintendo Co.*, 102 F.3d 1214, 1221 (Fed. Cir. 1996)).

Notwithstanding this clear history, the Federal Circuit recently established additional and conflicting standards for finding that prosecution arguments impliedly disclaim literal claim scope and equivalents protection. Rather than determining whether and to what extent – as viewed by competitors – claim language was narrowed (and thus presumptively or conclusively triggers an estoppel), courts must now review prosecution arguments for evidence of a clear and unmistakable disclaimer of patentable subject matter. In this case, the Federal Circuit cited for this new standard two earlier decisions, *Omega Engineering, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1326 (Fed. Cir. 2003) (relating to "prosecution disclaimer," or disclaimer of literal claim scope), and *Litton Systems, Inc. v. Honeywell, Inc.*, 140 F.3d 1449, 1458 (Fed. Cir. 1998) (relating to "argument-based estoppel," or disclaimer of equivalents protection). *See Cordis Corp.*, 339 F.3d at 1358, 1363. *See also Litton Sys.*, 140 F.3d at 1462-63. In turn, *Omega Engineering* cites to

various recent cases and then to *Litton Systems* and *Alpex Computer Corp.* *See* 334 F.3d at 1325, 1326 n.1. *Litton Systems* is mostly concerned with determining the existence of prosecution history estoppel and the rebuttal and scope of estoppel, but in finding prosecution disclaimers cites to *Hoganas AB* for the "clear and unmistakable" standard. 140 F.3d at 1458. The Federal Circuit's "clear and unmistakable" standards for prosecution disclaimer and argument-based estoppel thus conflict with its earlier, related standards regarding claim scope and estoppel.

The Federal Circuit's new standards will create additional confusion and will dramatically restrict the likelihood of finding a disclaimer from narrowing arguments, unjustly enriching patentees at the expense of competitors and the public. Under these standards, arguments that clearly narrow claims may no longer be held to disclaim literal scope or equivalents protection. These standards will thereby provide patentees with a greater scope of protection than they asked for and obtained from the Patent Office.[3] Moreover, whether the narrowing arguments respond to a proper examiner rejection or reflect unilateral recognition that the original claim is overly broad, the new standards may provide protection that patentees could not validly obtain

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[3] Similarly, courts may be less likely to find that ambiguous arguments trigger estoppel. Courts may erroneously apply the "clear and unmistakable" standard to determine whether narrowing has occurred. Alternatively, courts may avoid making any determination regarding narrowing, by finding that there is no clear and unmistakable disclaimer that would estop literal application of the claim or equivalents protection. Courts also improperly may begin to apply a "clear and unmistakable" standard to determining whether amendments narrow the claims).

from the Patent Office.[4] This is clearly improper. *See, e.g., Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 684 (Fed. Cir. 1990) ("a patentee should not be able to obtain, under the doctrine of equivalents, coverage which he could not lawfully have obtained from the PTO by literal claims. The doctrine of equivalents [does not] exist[]...to give a patentee something which he could not lawfully have obtained from the PTO had he tried.") (*citing Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950)).

The Federal Circuit new standards for argument-based disclaimers thus lack historic justification and their relation to other claim scope and estoppel standards is incoherent, because prosecution history claim construction and estoppel doctrines have common origins. Like claim construction, argument-based estoppel, and prosecution disclaimer, prosecution history "[e]stoppel is a 'rule of patent construction' that ensures that claims are interpreted by reference to those 'that have been cancelled or rejected.'" *Festo,* 535 U.S. at 733 (*quoting Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 220-221 (1940)). These doctrines were developed following adoption by Congress in the 1870 Patent Act of a requirement for distinct claims. *See* Act of July 8, 1870, § 26, 16 Stat. 198, 201 (requiring

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[4] The failure to find a disclaimer in regard to unpatentable subject matter is particularly likely for unenumerated embodiments of the original claims, *i.e.*, examples that were not actually disclosed in the specification. Patentees will argue that they could not have clearly and unmistakably disclaimed what they never described or discussed. *See Johnson & Johnson Assocs. v. R.E. Service Co.*, 285 F.3d 1046, 1052-56 (Fed. Cir. 2002) (en banc) (failure to claim disclosed subject matter dedicates that subject matter to the public); *id.* at 1060 (Dyk, J., concurring) (arguing that "dedication is a species of conscious waiver" that does not result from an invalid, overbroad claims encompassing equivalents).

specifications "particularly pointing out and distinctly claiming the part, improvement, or combination which he claims as his invention or discovery") (currently codified at 35 U.S.C. § 112, ¶ 2).

In numerous early cases, this Court prohibited patentees from "reclaiming" in reissued patents subject matter that they had formally disclaimed or had impliedly disclaimed, by failing to claim subject matter during initial prosecution or by adopting narrowing amendments and arguments during such prosecution. *See, e.g., Leggett v. Avery,* 101 U.S. 256, 259-60 (1879); *Goodyear Dental Vulcanite Co.,* 102 U.S. at 228; *Miller v. Bridgeport Brass Co.,* 104 U.S. 350, 352 (1881); *Mahn v. Harwood,* 112 U.S. 354, 360-61 (1884). As the Court stated in *Miller,* "it must be remembered that the claim of a specific device or combination, and an omission to claim other devices or combinations apparent on the face of the patent, are, in law, a dedication to the public of that which is not claimed." 104 U.S. at 352.

The implied-in-law disclaimer principles adopted in the early cases compelled the later result that patentees were estopped from asserting broader constructions of their claims in infringement actions than were allowed during prosecution in the Patent Office. *See, e.g., Hubbell v. United States,* 179 U.S. 77, 80 (1900) ("it is well settled that the claim as allowed must be read and interpreted with reference to the rejected claim and to the prior state of the art, and cannot be so construed as to cover either what was rejected by the Patent Office or disclosed by prior devices.... [The patentee] is not allowed to revive a rejected claim by a broad construction of the claim allowed....") (citations omitted);

Knapp v. Morss, 150 U.S. 221, 224-25, 229 (1893) (same).[5] These principles also compelled the result that patentees could not argue for broader constructions of claims in infringement actions than were supported by a proper construction of their arguments and amendments in the Patent Office. *See, e.g., Weber Elec. Co. v. E.H. Freeman Elec. Co.,* 256 U.S. 668, 677-78 (1921) ("Having thus narrowed his claim ... in order to obtain a patent the patentee may not by construction, or by resort to the doctrine of equivalents, give to the claim the larger scope which it might have had without the [arguments and] amendments, which amount to a disclaimer"); *I.T.S. Rubber Co. v. Essex Rubber Co.,* 272 U.S. 429, 443-44 (1926) ("having limited his claim by amendment... limitations imposed by the inventor... must be strictly construed against the inventor and looked upon as disclaimers.").

III. The "Clear and Unmistakable" Disclaimer Standard Will Harm Competitors and the Public By Increasing The Uncertainty or Scope of Virtually Every Patent.

As a result of this Court's decision in *Markman v. Westview Instruments, Inc.,* 517 U.S. 370 (1996) – as implemented by the Federal Circuit – construction of patent claim scope is reviewed *de novo, i.e.,* without any deference

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[5] Further, the doctrine of equivalents was limited until 1950 to determining equivalency within the scope of construed claim language. *See generally* Ronald D. Hantman, *Doctrine of Equivalents,* 70 J. PAT & TRADEMARK OFF. SOC'Y 511 (1988). Thus, these estoppel doctrines were historically applied only to limit later-filed claims and to interpret the scope of narrowed claims, not to determine disclaimer in regard to equivalents outside the scope of application of construed claims.

to the trial court's interpretation. *See Cybor,* 138 F.3d at 1456. The Federal Circuit reverses trial courts on claim construction issues in approximately one half of all the cases that it considers. *See* Institute for Intellectual Property and Information Law, University of Houston Law Center, Decisions for 2002, *at* http://www.patstats.org/2002.html (last visited Feb. 3, 2004). Three-fourths of the findings of infringement under the doctrine of equivalents are reversed (although most of the findings that the doctrine does not apply are sustained). *See id.* Thus, patent scope is highly uncertain and cannot easily be determined prior to litigation and appeal. Patent litigation through appeal is both protracted and expensive.

The Federal Circuit's "clear and unmistakable" disclaimer standard will create even more uncertainty over claim interpretation and equivalents protection. Virtually every patent is issued after some argument is offered by the patentee (with or without an amendment), in order to respond to an initial rejection of some of the claims by the Patent Office. Thus, in virtually every patent the existence and scope of an argument-based estoppel will be at issue. Trial judges and appellate judges will now dispute whether statements made during prosecution are "clear and unmistakable," just as they commonly differ regarding the meaning of claim language. Absent protracted and expensive litigation, competitors and the public will be even less able to determine the scope of issued patents.

The restrictive nature of the Federal Circuit's "clear and unmistakable" disclaimer standard also will prevent a finding of disclaimer in many cases where a reasonable competitor would believe that patent scope was disclaimed. In those cases, patentees will be able to assert broad claim constructions and to resort to the doctrine of equivalents.

The patentee thus will obtain additional patent protection that did not exist before the Federal Circuit's recent change in the law applicable to argument-based disclaimers.

The threat and cost of litigation, combined with the increasingly uncertain and expanded scope of patent protection, will discourage innovators and competitors from inventing and marketing new goods and services. "If competitors cannot be certain about a patent's extent, they may be deterred from engaging in legitimate manufactures outside its limits, or they may invest by mistake in competing products that the patent secures." *Festo,* 535 U.S. at 732. Rather than face litigation, many competitors will chose not to innovate. This will result in fewer alternative patented goods in the marketplace. Products that do enter the marketplace will likely be offered at a higher cost due to the expenses associated with designing around uncertain patents and litigation. The result will cause substantial public harm.

> "The limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject matter of the patent will be dedicated ultimately to the public." ... Otherwise, a "zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field," ... and "[t]he public [would] be deprived of rights supposedly belonging to it, without being clearly told what it is that limits those rights."

Markman, 517 U.S. at 390 (citations omitted). These harms are discussed in greater detail in the brief *amicus curiae* filed in this Court by the undersigned counsel for the Consumer Project on Technology in the *Festo* case.

Conclusion

The "clear and unmistakable" disclaimer standard adopted by the Federal Circuit in this case is in conflict with this Court's decision in *Festo*, is in conflict with the Federal Circuit's other standards, unjustly enriches patentees, lacks historic justification, and will result in substantial harm to the public. On February 3, 2004, counsel for Shoketsu Kinzoku Kogyo Kabushiki Co. submitted a petition for certiorari in the *Festo* case, following the en banc decision of the Federal Circuit on remand from this Court. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359 (Fed. Cir. 2003) (en banc). That petition argues that the Federal Circuit departed from the estoppel standards articulated by this Court. The Court should grant both the petition in this case and the petition in *Festo* in order to clarify the proper standards for finding narrowing and for finding estoppel in regard to both claim scope and equivalents protection.

Respectfully submitted,

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